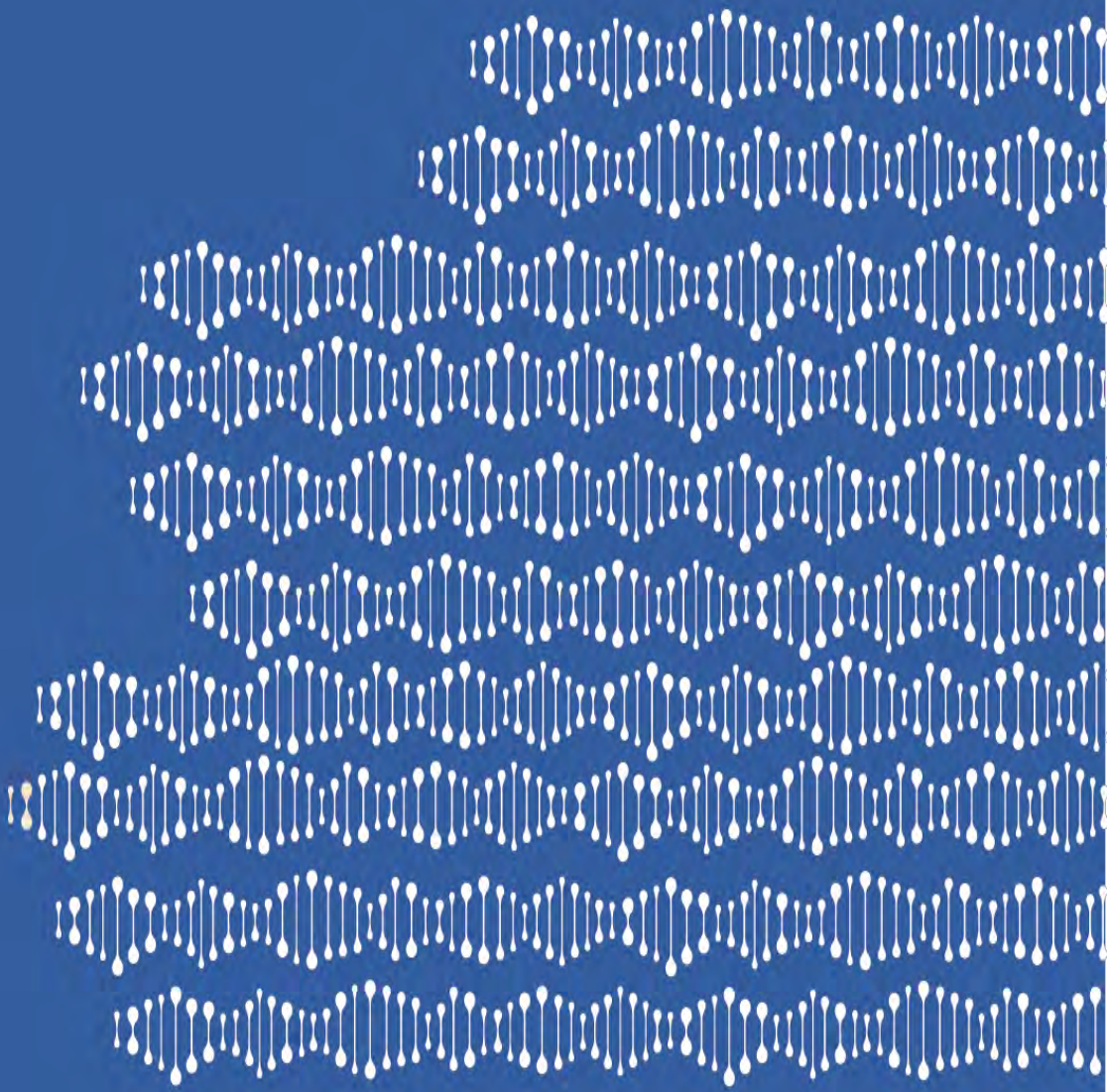
CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

Oversight Committee Meeting

February 21, 2019



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

Oversight Committee Meeting Agenda

Texas Higher Education Coordinating Board
1200 E. Anderson Lane, Austin, TX 78752
Board Room 1.170

February 21, 2019
10:00 a.m.

The Oversight Committee may discuss or act on any item on this agenda, and as authorized by the Texas Open Meetings Act, Texas Government Code Section 551.001 et seq., may meet in closed session concerning any purpose permitted by the Act. Anyone wishing to offer public comments must notify the Chief Executive Officer in writing prior to the start of the meeting. The Committee may limit the time a member of the public may speak.

1. Call to Order
2. Roll Call/Excused Absences
3. Adoption of Minutes from the November 28, 2018, meeting — Tab 1
4. Public Comment
5. Grantee Presentation — Tab 2
6. Chief Executive Officer Report — Tab 3
7. Chief Compliance Officer Report — Tab 4
8. Chief Scientific Officer Report — Tab 5
   - Grant Award Recommendations
9. Chief Prevention and Communications Officer Report — Tab 6
   - Grant Award Recommendations
   - FY 2020 Requests for Applications and Timeline
10. Chief Product Development Officer Report — Tab 7
    - Grant Award Recommendations
    - FY 2020 Requests for Applications and Timeline
11. Advisory Committee on Childhood Cancer Annual Report — Tab 8
12. Scientific Research and Prevention Program Committee Appointments — Tab 9
13. University Advisory Committee Appointments — Tab 10
14. Internal Auditor Report — Tab 11
    - Internal Audit Follow-Up Procedures Report over Performance Measures
    - Internal Audit Report on State Reporting
    - Internal Audit Report on Budget and Planning
15. Amendments to 25 T.A.C. Chapter 703 — Tab 12
    - Final Order Approving Amendments to Chapter 703
    - Proposed Amendments to Chapter 703 and Authorization to Publish in *Texas Register*
16. Chief Operating Officer Report — Tab 13
17. Subcommittee Business
18. Compliance Investigation Pursuant to Health & Safety Code § 102.2631
19. Consultation with General Counsel
20. Future Meeting Dates and Agenda Items
21. Adjourn

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

Summary Overview of the February 21, 2019, Oversight Committee Meeting

This summary provides an overview of major agenda items and background on key issues for Committee consideration at the February 21, 2019, Oversight Committee meeting.

CEO Report
Wayne Roberts will present the CEO's report and address issues including personnel, CPRIT's 2018 Annual Report, CPRIT's new website, status of legislation affecting CPRIT, FY19 grant award funds available, and other topics.

Chief Compliance Officer Report
Vince Burgess will report on the status of required grantee reports, financial status report reviews, desk reviews and site visits, annual compliance attestation, single audit tracking, and training.

Chief Scientific Officer Report and Grant Award Recommendations
Dr. James Willson will provide an update on the Academic Research Program and present the Program Integration Committee's (PIC) 42 award recommendations for Individual Investigator Research Awards (IIRA); IIRA for Cancer in Children and Adolescents; IIRA for Clinical Translation; IIRA for Computational Biology; IIRA for Prevention and Early Detection; Recruitment of First-Time, Tenure-Track Faculty Members; and Recruitment of Rising Stars.

CPRIT does not publicly disclose information related to the Academic Research grant applications recommended for funding until the Oversight Committee meeting. The information is available to board members through a secure electronic portal.

Chief Prevention and Communications Officer Report and Grant Award Recommendations
Dr. Becky Garcia will update the Oversight Committee on the on the agency's prevention program and present the PIC's seven award recommendations for Tobacco Control and Lung Cancer Screening; Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations; and Dissemination of CPRIT-Funded Cancer Control Interventions. She will also report on CPRIT's communications activities.

CPRIT does not publicly disclose information related to the Prevention grant applications recommended for funding until the Oversight Committee meeting. The information is available to board members through a secure electronic portal.

Chief Product Development Officer Report and Grant Award Recommendations

CPRIT Interim Chief Product Development Officer Kristen Doyle will provide an update on the Product Development Program and present the PIC's five award recommendations for: Texas

PO Box 12097 | Austin, Texas 78711 | PH: 512-463-3190 | F: 512-475-2563 | cprit.texas.gov

Company Product Development Awards, Company Relocation Product Development Research Awards, and Seed Awards for Product Development Research.

CPRIT does not publicly disclose information related to the Product Development Research grant applications recommended for funding until the Oversight Committee meeting. The information is available to board members through a secure electronic portal.

Advisory Committee on Childhood Cancer (ACCC) Annual Report
By its charter, the ACCC is required to present its annual report to the Oversight Committee. Dr. Stephen X. Skapek, M.D., will present the ACCC report.

Appointments - Scientific Research and Prevention Programs Committee
Mr. Roberts has provisionally appointed 10 new members to CPRIT's Scientific Research and Prevention Programs Committees. CPRIT's statute requires the Oversight Committee to approve the CEO's recommendations before the appointments are final.

Appointments – University Advisory Committee (UAC)
Pursuant to Tex. Health & Safety Code § 102.154, chancellors at the various university systems detailed in the statute appoint members of the UAC. One new member has been appointed to represent Southern Methodist University.

Internal Auditor Report
Weaver and Tidwell, CPRIT's internal auditor, will provide an internal audit update and will present three internal audit reports.

Amendments to 25 TAC Chapters 703
Cameron Eckel will present the final order approving amendments to Chapter 703 that the Oversight Committee provisionally approved at the November meeting. If approved, the amendment will become effective in March.

Ms. Eckel will also present proposed changes to the agency's administrative rules in Chapter 703. Texas Health and Safety Code § 102.108 authorizes the Oversight Committee to implement rules to administer CPRIT's statute. Legal staff will bring back these rule changes to the Oversight Committee for final approval in May after the public has commented on the proposed rule changes.

Chief Operating Officer Report
Heidi McConnell will discuss the operating budget, performance measures, and debt issuance history for the first quarter of FY 2019.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

Oversight Committee Meeting
November 28, 2018

NOTE: Unless the information is confidential, the reports, presentations, and grant award information referenced in the minutes are available at http://ocmeetings.cprit.texas.gov in the "Meeting Packet" section for the corresponding meeting date.

Call to Order – Agenda Item 1

A quorum being present, Presiding Officer Will Montgomery called the Oversight Committee to order at 10:02 a.m.

Oath of Office for David A. Cummings, M.D. – Agenda Item 3

Presiding Officer Montgomery administered the oath of office to Dr. Cummings. Governor Greg Abbott appointed Dr. Cummings to the Oversight Committee for a term expiring January 31, 2023.

Roll Call/Excused Absences – Agenda Item 2

Committee Members Present	Committee Members Absent
Bill Rice, M.D.	Donald (Dee) Margo
Craig Rosenfeld, M.D.	Angelos Angelou
Will Montgomery	
Mahendra Patel, M.D.	
David Cummings, M.D.	

MOTION:
On a motion by Dr. Rice and seconded by Dr. Rosenfeld, the Oversight Committee unanimously voted to approve the excused absences of Mr. Margo and Mr. Angelou.

Adoption of Minutes from the August 24, 2018 Meeting – Agenda Item 4 – Tab 1

MOTION:
On a motion by Dr. Rice and seconded by Dr. Rosenfeld, the Oversight Committee unanimously voted to approve the minutes of the Oversight Committee meeting of August 24, 2018, as presented.

Public Comment – Agenda Item 5

There were no requests to provide public comment.

Grantee Presentation – Agenda Item 6 – Tab 2

Dr. Willson introduced CPRIT grantee, Livia Eberlin, Ph.D., assistant professor in the Department of Chemistry at the University of Texas at Austin.

Dr. Eberlin provided an overview of the development of the MasSpec Pen and its potential as a tool for real time cancer diagnostics. She discussed her CPRIT-funded research that supports collaborations between her program at UT Austin and surgeons at MD Anderson and Baylor College of Medicine to evaluate the MasSpec Pen for diagnosis of thyroid (RP170427), lung (RP160776), and ovarian (RP180381) cancers. Dr. Eberlin acknowledged the opportunities that her CPRIT funding has enabled and the unique translational research resources in Texas that has accelerated her research forward.

Dr. Eberlin's presentation was enthusiastically received and led to several questions by the Oversight Committee members regarding the mass spectroscopy technology and potential application beyond those cancers discussed.

Presiding Officer Montgomery recognized Dr. Eberlin for her recent 2018 MacArthur Foundation Fellowship. Presiding Officer Montgomery also noted that Dr. Jim Allison of UT MD Anderson Cancer Center received the 2018 Nobel Prize in Medicine and Dr. Zhijian "James" Chen of UT Southwestern received the 2019 Breakthrough Prize.

Chief Executive Officer Report – Agenda Item 7 – Tab 3

Presiding Officer Montgomery recognized Mr. Roberts for the CEO report.

Mr. Roberts reported that the interviews for a new Chief Product Development Officer would begin the following week and that CPRIT should fill the position by late January.

He stated that the approval of today's award recommendations would leave more than $260 million in grant award funds remaining for fiscal year 2019.

Mr. Roberts highlighted current legislation of interest to CPRIT, reporting that Representative Zerwas, a physician from Fort Bend County, pre-filed a bill to increase the bonding authority for CPRIT from $3 billion to $6 billion (HJR 12) as well as a second bill repealing the prohibition against CPRIT making new awards after August 31, 2022 (HB39). Mr. Roberts also reported that Senator Schwertner pre-filed a bill requiring CPRIT to develop a plan for self-sufficiency (SB200). He noted that Senator Schwertner's bill contains the same text from self-sufficiency bills he has filed in previous sessions. Mr. Roberts indicated that CPRIT has included discussion of self-sufficiency in its statutorily required annual report for the past two years.

He directed members to the Texas Cancer Momentum Report and other draft handouts relating to CPRIT's reauthorization, budget, and means of funding. The finalized documents will be sent to the members electronically.

Mr. Roberts concluded his report noting that he and other CPRIT staff traveled to 15 events around the state in the past two months. The American Cancer Society Cancer Action Network (ACS CAN)

and Texas Healthcare and Bioscience Institute hosted most of the events. He noted that Cam Scott with (ACS CAN) has taken another job out of state, but that James Gray would take his place on an interim basis.

Chief Compliance Officer Report – Agenda Item 8 – Tab 4

Presiding Officer Montgomery recognized Vince Burgess, Chief Compliance Officer. Mr. Burgess presented the Compliance Report for the past quarter's activities, noting that the number of delinquent reports in fiscal year 2018 showed a slight increase from fiscal year 2017, with an average of 18 reports per month. He reported that the increase is attributable to the change in Matching Compliance Certification (MCC) form reporting requirements in CGMS, as mentioned in previous meetings.

Mr. Burgess discussed the chart on page 4-4 of the meeting booklet showing data from the last four fiscal years.

A committee member asked Mr. Burgess if his team reached out to grantees with recurring issues. He confirmed that Compliance provides additional, targeted training to grantees on an as-needed basis.

Chief Scientific Officer Report – Agenda Item 9 – Tab 5

Presiding Officer Montgomery recognized CPRIT Chief Scientific Officer Dr. Jim Willson to present the academic research program update and the award slate recommended by the CPRIT Scientific Review Council (SRC) and the Program Integration Committee (PIC).

Dr. Willson referred the members to pages 5-1 and 5-2 of the meeting book describing the Request for Applications (RFA) planning and explained that, given the reduced funding available to CPRIT in Fiscal Years 2020 and 2021, CPRIT's Academic Research Program plans to reduce the number of annual grant cycles. Instead of two grant cycles per year, Academic Research will offer one application cycle in 2020 that will include the following grant mechanisms:

- Individual Investigator Research Awards (untargeted)
- Individual Investigator Research Awards for Cancer in Children and Adolescents
- Individual Investigator Research Awards for Prevention and Early Detection
- Individual Investigator Research Awards for Clinical Translation

CPRIT will continue to offer always-open Recruitment RFAs.

Responding to a committee member's question, Dr. Willson agreed that if the Legislature approves CPRIT's request for general revenue in the upcoming legislative session to maintain the amount available for grants at the same level as previous years, the academic research program will offer a second grant application cycle in Fiscal Year 2020.

In response to a committee member's inquiry regarding the practicality of issuing a Core Facility Support RFA in the final years of CPRITs award authority to support facility construction, Dr. Willson and Mr. Roberts noted that the core facility support awards do not fund construction of new facilities and explained that the award supports access to cutting-edge technology for cancer researchers.

Dr. Willson presented the Program Integration Committees grant award recommendations for Fiscal Year 2019 first quarter recruitment cycles 19.1, 19.2 and 19.3. The slate included two Established Investigators and two First-Time, Tenure Track Faculty Member nominations.

Rank	App ID	Candidate	Mechanism	Organization	Budget	Score
1	RR190003	Ansuman Satpathy, M.D., Ph.D.	RFTFM	Baylor College of Medicine	$2,000,000	1.0
2	RR190017	Matthew Gubin, Ph.D.	RFTFM	The University of Texas M. D. Anderson Cancer Center	$2,000,000	1.5
3	RR190009	Thomas D. Wang, M.D., Ph.D.	REI	The University of Texas Southwestern Medical Center	$6,000,000	1.8
4	RR190015	Shideng Bao, Ph.D.	REI	The University of Texas Health Science Center at San Antonio	$6,000,000	2.0

Presiding Officer Montgomery noted that the outstanding scores of the candidates reflects on the ability of academic institutions to attract top candidates and the success of CPRITs Scholar's initiative.

Dr. Rice requested that Dr. Willson present data on the success rate of the recruitment to Texas of CPRIT Scholar applicants approved by the Scientific Review Council at the next Oversight Committee meeting in February 2019.

Compliance Certification

Mr. Burgess' presented the compliance certification report for the proposed academic research grant awards.

Conflict of Interest Notification

Presiding Officer Montgomery noted that no Oversight Committee member reported a conflict of interest with any applications under consideration.

MOTION:
On a motion made by Dr. Rice and seconded by Dr. Rosenfeld the Oversight Committee unanimously voted to approve the Program Integration Committee's recommendations for the Recruitment of Established Investigators and Recruitment of First-Time, Tenure-Track Faculty Members.

MOTION:
On a motion made by Dr. Rice and seconded by Dr. Rosenfeld the Oversight Committee unanimously voted to approve the delegation of contract negotiation authority to CPRIT's CEO and staff and authorized the CEO to sign the contracts on behalf of CPRIT.

MOTION:
On a motion made by Dr. Rice and seconded by Dr. Patel the Oversight Committee unanimously voted to approve the proposed fiscal year 2020 Cycle 1 Requests for Applications and timeline as recommended by Dr. Willson.

Chief Prevention and Communications Officer Report – Agenda Item 10 – Tab 7

Presiding Officer Montgomery recognized Chief Prevention and Communications Officer Dr. Becky Garcia to provide an update on the prevention program. Dr. Garcia gave a brief overview of the first cycle of grant applications for fiscal year 2019 and the RFAs CPRIT will issue for the second cycle.

Dr. Garcia responded to an Oversight Committee member's question regarding whether CPRIT funds therapeutic prevention studies, explaining that CPRIT's Academic Research program offers a funding mechanism, Individual Investigator Research Awards for Prevention and Early Detection, that supports applications addressing questions that will advance knowledge of the causes, prevention, progression, and/or early detection of cancer.

Communications Report

Dr. Garcia highlighted the soft launch of the new CPRIT website scheduled for November 30. She reported that staff will send a link to the members when the site is live. The site has a new design, new platform and retains the statutorily required content. In addition, it has new features such as an "Our Impact" section, digital newsroom, and new CPRIT Scholar section. She recognized the IT and Communications staff for their hard work.

Dr. Garcia also reported that the CPRIT Conference request for proposals received no responses so CPRIT will repost it with changes. She noted that the state hotel reimbursement rate is limiting some hotels' interest, but CPRIT is still looking at the summer of 2020 in surrounding cities. Dr. Rosenfeld suggested including hotels on South Padre Island.

Chief Product Development Officer Report – Agenda Item 11 – Tab 6

Presiding Officer Montgomery recognized Kristen Doyle, Interim Chief Product Development Research Officer, to present the Product Development Research Program update.

Ms. Doyle presented a brief update on Product Development Research Program and referred members to her memo included in the meeting packet at Tab 7. She noted that the Chief Product Development Officer will bring award recommendations for the first cycle of fiscal year 2019 to the Oversight Committee in February. She also reported that CPRIT will release three new Product Development Program requests for applications in early December. Ms. Doyle summarized the CPRIT Product Development program priorities for fiscal year 2020. The Product Development Research Program

did not propose any changes to the priorities that the Oversight Committee originally adopted for fiscal year 2019.

Mr. Roberts responded to an Oversight Committee member's question about the search process for the new Chief Product Development Officer, reviewing the steps taken in the search.

Presiding Officer Montgomery thanked Ms. Doyle for serving as Interim Chief Product Development Officer. Ms. Doyle recognized Rosemary French, Senior Program Manager for Product Development, for her assistance.

Scientific Research and Prevention Program Committee Appointments – Agenda Item 12 – Tab 8

Presiding Officer Montgomery recognized Mr. Roberts to present his 21 peer review appointments. Mr. Roberts noted that the Nominations Subcommittee discussed the appointments at its meeting on November 9 and recommended that the Oversight Committee vote to approve the appointments. He noted that CPRIT made bio sketches available electronically.

MOTION:
On a motion by Dr. Rosenfeld and seconded by Dr. Rice, the Oversight Committee unanimously voted to approve the Scientific Research Program Committee appointments.

Mr. Roberts informed the Oversight Committee of two new appointments to the University Advisory Committee: Dr. Claudia Neuhaser, Associate Vice Chancellor/Associate Vice President for Research and Technology Transfer at the University of Houston and Dr. Peter Davies, Head of the Institute of Biosciences and Technology and Professor at the Translational Cancer Center at Texas A&M University. Pursuant to CPRIT's statute, the chancellors of the various Texas institutions are responsible for appointing members to the University Advisory Committee and no Oversight Committee action was necessary.

Advisory Committee on Childhood Cancer Appointments – Agenda Item 13 – Tab 9

Presiding Officer Montgomery recognized Mr. Roberts to present the three proposed appointments to the Advisory Committee on Childhood Cancers. He reported that the Nominations subcommittee reviewed the Presiding Officer's appointments at the November 9 subcommittee meeting and recommended that the Oversight Committee vote to approve the appointments.

MOTION:
On a motion by Dr. Rice and seconded by Dr. Rosenfeld, the Oversight Committee unanimously voted to approve the three proposed appointments to the Advisory Committee on Childhood Cancer.

Fiscal Year 2020 Program Priorities - Agenda Item 14 – Tab 10

Presiding Officer Montgomery recognized Mr. Roberts to present the fiscal year 2020 Program Priorities for the Oversight Committee's consideration.

MOTION:
On a motion made by Dr. Rice and seconded by Dr. Rosenfeld, the Oversight Committee unanimously voted to approve the fiscal year 2020 program priorities.

Internal Auditor Report – Agenda Item 15 – Tab 11

Presiding Officer Montgomery recognized CPRIT's internal auditor, Dan Graves with Weaver and Tidwell, LLP, to present the status update on the fiscal year 2019 internal audit plan and schedule. Mr. Graves delivered the report, noting that the fieldwork for the State Reporting Internal Audit and State Auditor's Office Performance Measures Follow Up Procedures began October 22, 2018.

Responding to an Oversight Committee member's question, Mr. Graves clarified that the internal audit includes an evaluation of risks and internal controls in place related to CPRIT's State Reporting practices. Activities considered in the evaluation include Annual Reports, Research/Analytical Supporting, the Texas Cancer Plan, Public Information Act Requests, and Ad Hoc Reporting.

He went on to explain that the Budget and Planning Internal Audit would begin next week, and that they plan the remaining follow-up procedures for February 2019. At Presiding Officer Montgomery's direction, he explained the chart on 11-4.

Amendments to 25 T.A.C. Chapters 703 – Agenda Item 16 – Tab 12

Presiding Officer Montgomery recognized Ms. Cameron Eckel, staff attorney, to present the final orders and new proposed rule changes to Texas Administrative Code Chapter 703. Ms. Eckel reported that the Board Governance subcommittee recommended the adoption of the proposed administrative rule changes to Chapter 703 as originally considered at the August meeting. She stated that CPRIT will submit the approved amendments to the Secretary of State and the changes will be effective 20 days later. Ms. Eckel also reported that the Board Governance subcommittee recommended publication of new proposed rule amendments to Chapter 703 in the *Texas Register* for public comment. These rule amendments will be brought back to the Oversight Committee for final adoption at the meeting in February.

MOTION:
On a motion by Dr. Rice and seconded by Dr. Rosenfeld, the Oversight Committee unanimously voted to approve the final orders adopting rules changes to the Texas Administrative Code Chapters 703.

MOTION:
On a motion by Dr. Rice and seconded by Dr. Rosenfeld, the Oversight Committee unanimously voted to approve the publication of the proposed changes to the Texas Administrative Code Chapter 703 in the *Texas Register*.

Amendments to the Oversight Committee Bylaws– Agenda Item 17 – Tab 13

Presiding Officer Montgomery recognized Ms. Doyle to explain the proposed change to the Oversight Committee bylaws. Ms. Doyle reported that the proposed change will require the Oversight Committee members to received periodic training.

MOTION:
On a motion by Dr. Rice and seconded by Dr. Rosenfeld, the Oversight Committee unanimously voted to approve the change to the Oversight Committee bylaws section 3.15.

Chief Operating Officer Report – Agenda Item 18 – Tab 14

Presiding Officer Montgomery recognized Heidi McConnell to present the Chief Operating Officer's Report. Ms. McConnell reported that grantees paid $186,000 in revenue sharing. She also reviewed debt issuance and explained that $1.5 billion debt had been issued over the life of the agency and Texas Public Finance Authority predicted $2.9 billion in principal and $1.6 billion in interest would be issued through 2049.

Dr. Rosenfeld inquired if interest rates affected bonds. Ms. McConnell responded that interest rates do affect bonds and directed members to percentage calculations by the Texas Public Finance Authority.

Subcommittee Business – Agenda Item 19 – Tab 14

Presiding Officer Montgomery announced that he appointed new Oversight Committee member Dr. Cummings to serve as a member of the Prevention and Audit Subcommittees.

MOTION:
On a motion by Dr. Rosenfeld and seconded by Dr. Rice, the Oversight Committee unanimously voted to approve Dr. Cummings' appointments to the Prevention and Audit subcommittees.

Compliance Investigation Pursuant to Health & Safety Code 102.2631 – Agenda Item 20
Consultation with General Counsel – Agenda Item 21

Presiding Officer Montgomery announced that standing items 20 and 21 would not be taken up.

Future Meeting Dates and Agenda Items – Agenda Item 22

Presiding Officer Montgomery informed members that the next Oversight Committee meeting will occur on Thursday, February 21, 2019 at the Texas Higher Education Coordinating Board.

Adjourn – Agenda Item 23

MOTION:
There being no further business, the Oversight Committee unanimously approved a motion to adjourn made by Dr. Rosenfeld and seconded Dr. Patel.

Meeting adjourned at 12:23 p.m.

Signature

Date

The Texas Hepatocellular Carcinoma Consortium (THCCC)

Hashem B El-Serag, MD, MPH

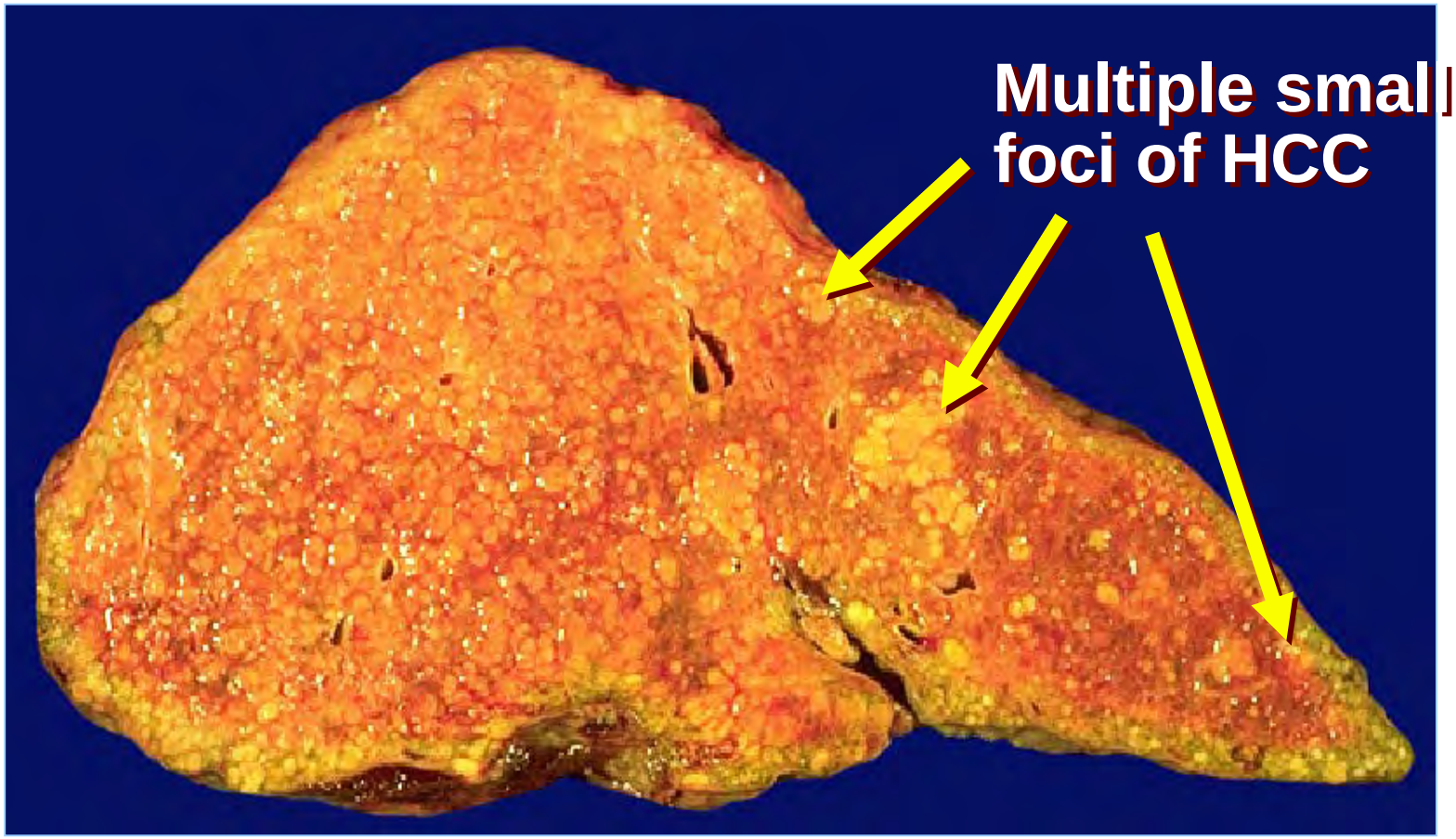
Margaret and Albert Alkek Professor and

Chair, Department of Medicine

Baylor College of Medicine

Houston, Texas

Hepatocellular Carcinoma (HCC) in a Liver with Cirrhosis



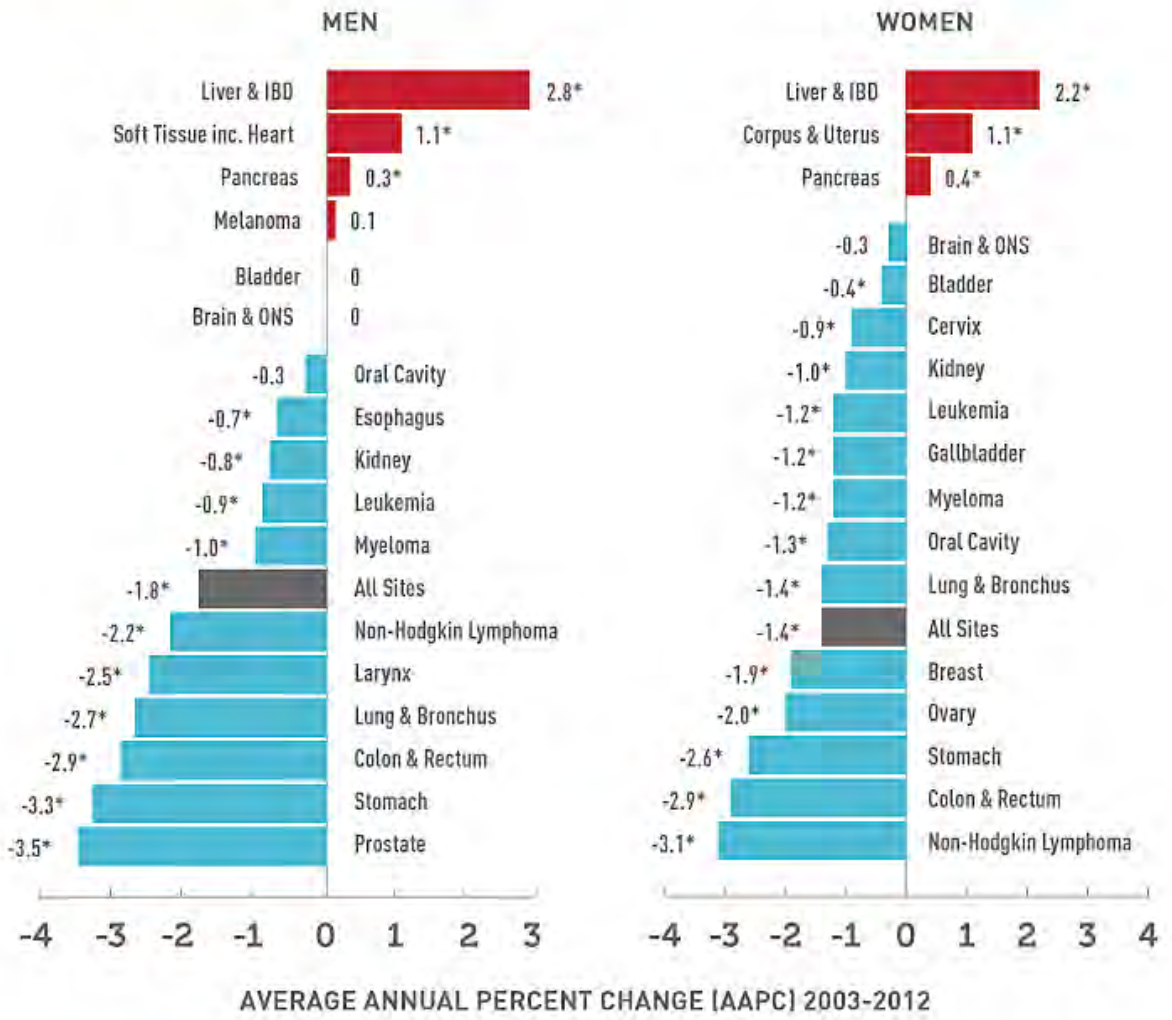
The New England Journal of Medicine

Established in 1812 as THE NEW ENGLAND JOURNAL OF MEDICINE AND SURGERY

VOLUME 340 MARCH 11, 1999 NUMBER 10

ORIGINAL ARTICLES

NATIONAL CANCER INSTITUTE
10-YEAR MORTALITY TRENDS



*AAPC is significantly different from zero (p<.05).

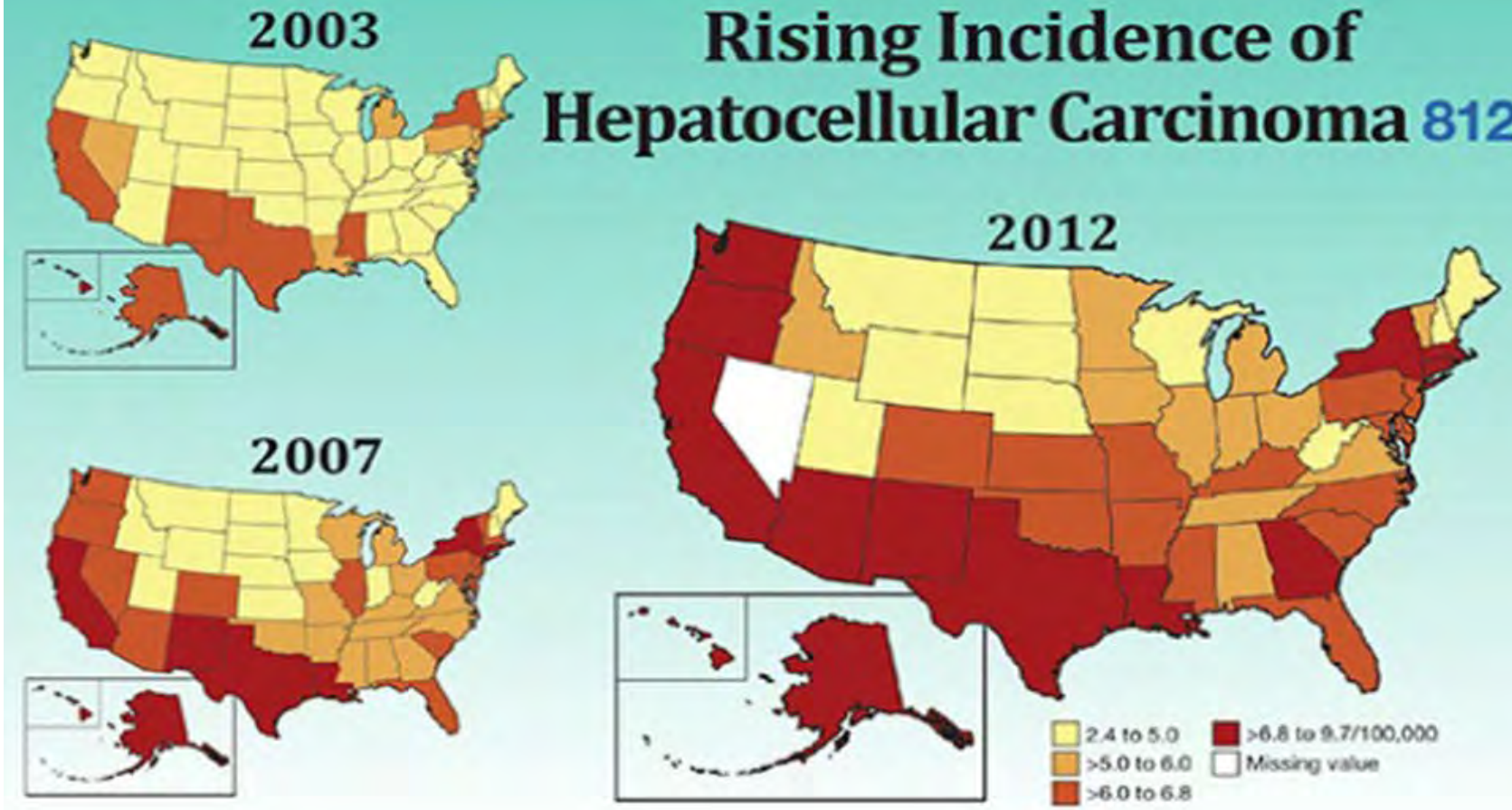
www.cancer.gov

Source: Annual Report to the Nation on the Status of Cancer 1975-2012

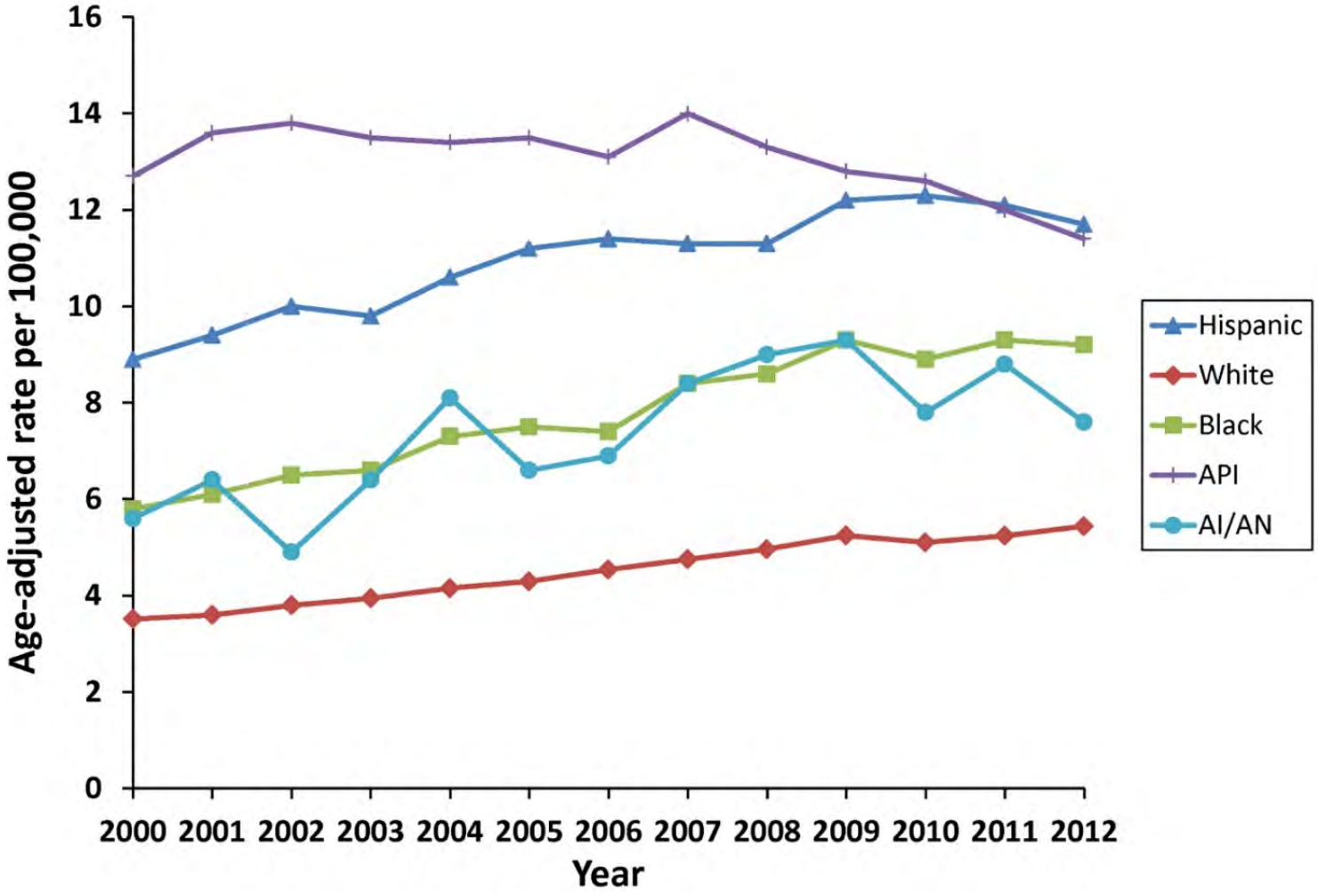
Gastroenterology

www.gastrojournal.org Volume 152 Number 4 March 2017

Rising Incidence of Hepatocellular Carcinoma 812

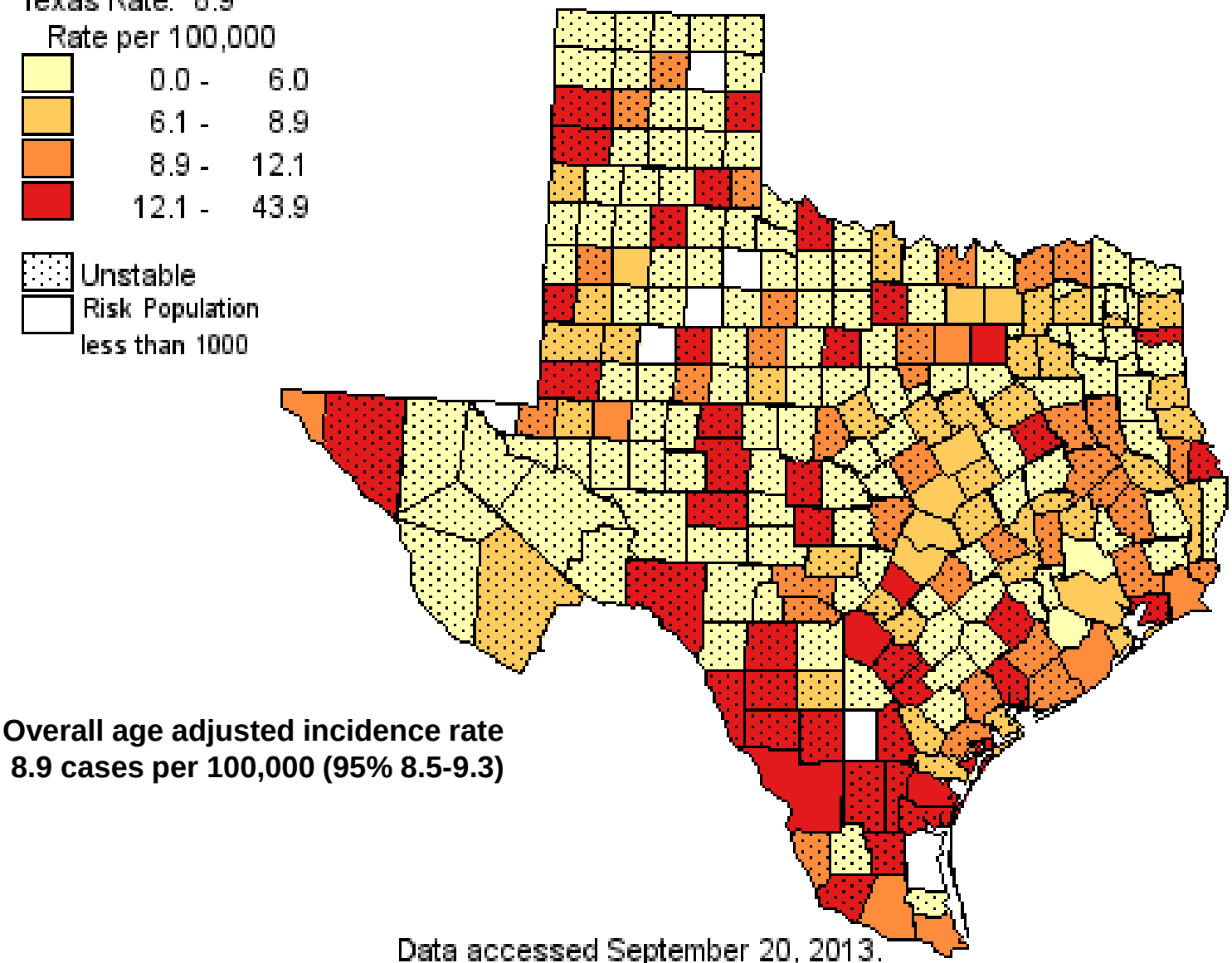


Age-adjusted HCC Incidence Rates in the United States between 2000 and 2012



Gastroenterology 2017 152, 812-820

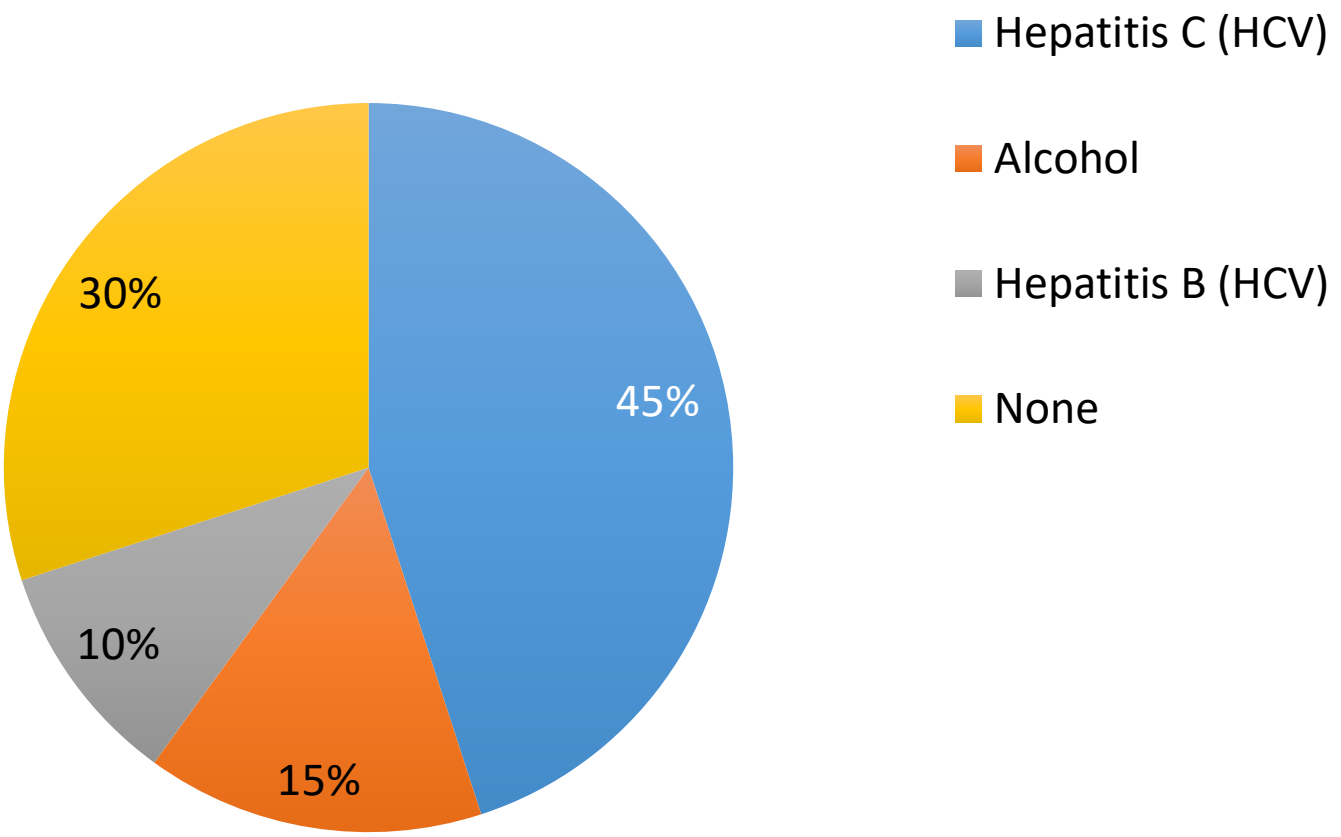
Age-Adjusted Invasive Cancer Incidence Rates in Texas
Liver, 2010
By County
Age-Adjusted to the 2000 U.S. Standard Population
Texas Rate: 8.9



Overall age adjusted incidence rate
8.9 cases per 100,000 (95% 8.5-9.3)

Data accessed September 20, 2013.
Cancer Incidence File, April 2013.

Major Risk Factors for HCC in the United States



Factors Associated With Increased HCC Risk in Patients with Active HCV Infection

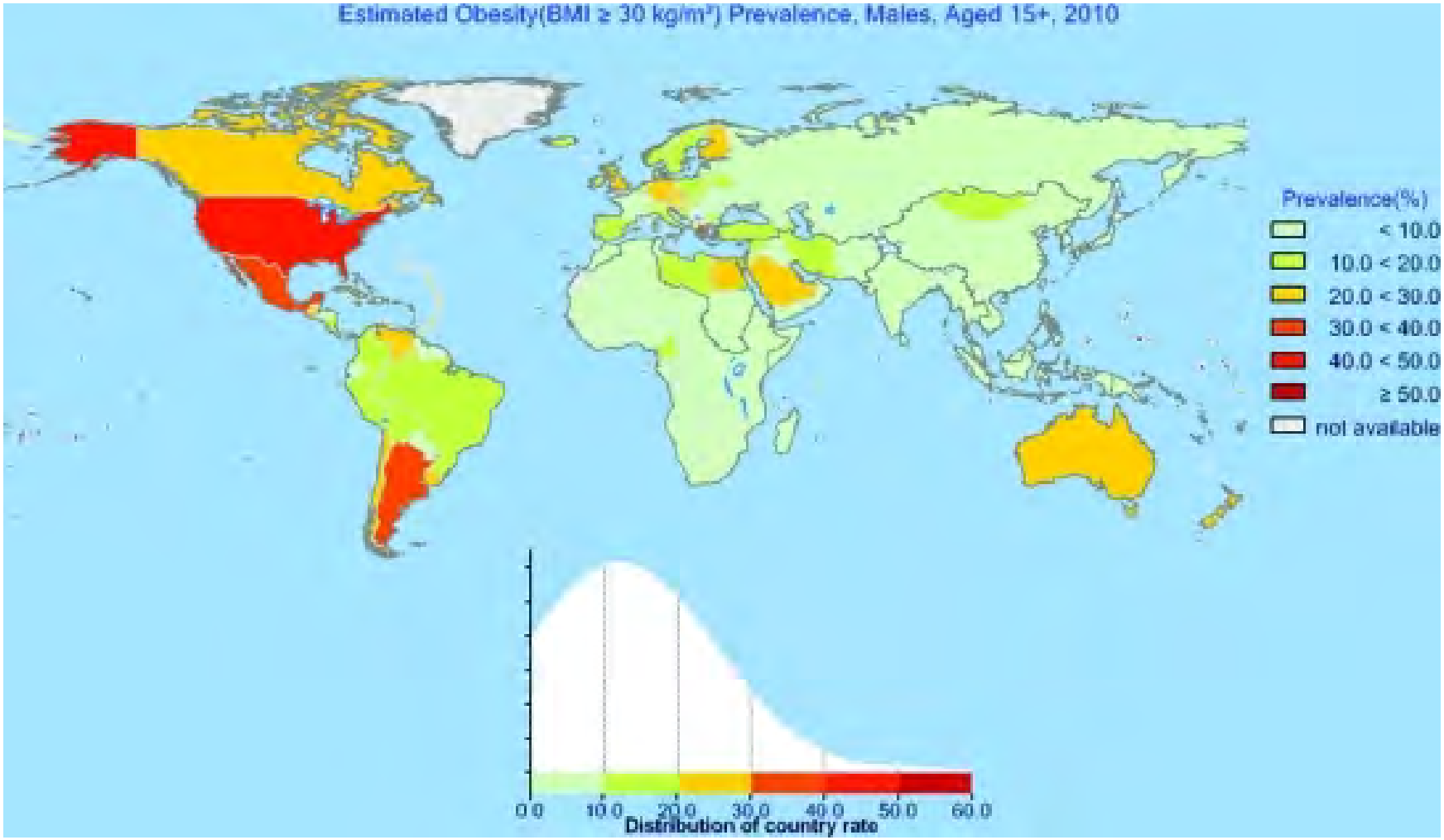
- **Mod**
  - –
  - –
  - –
  - –
- Non-
  - –
  - –
  - –

with HBV or HIV

Antiviral Treatment with SVR

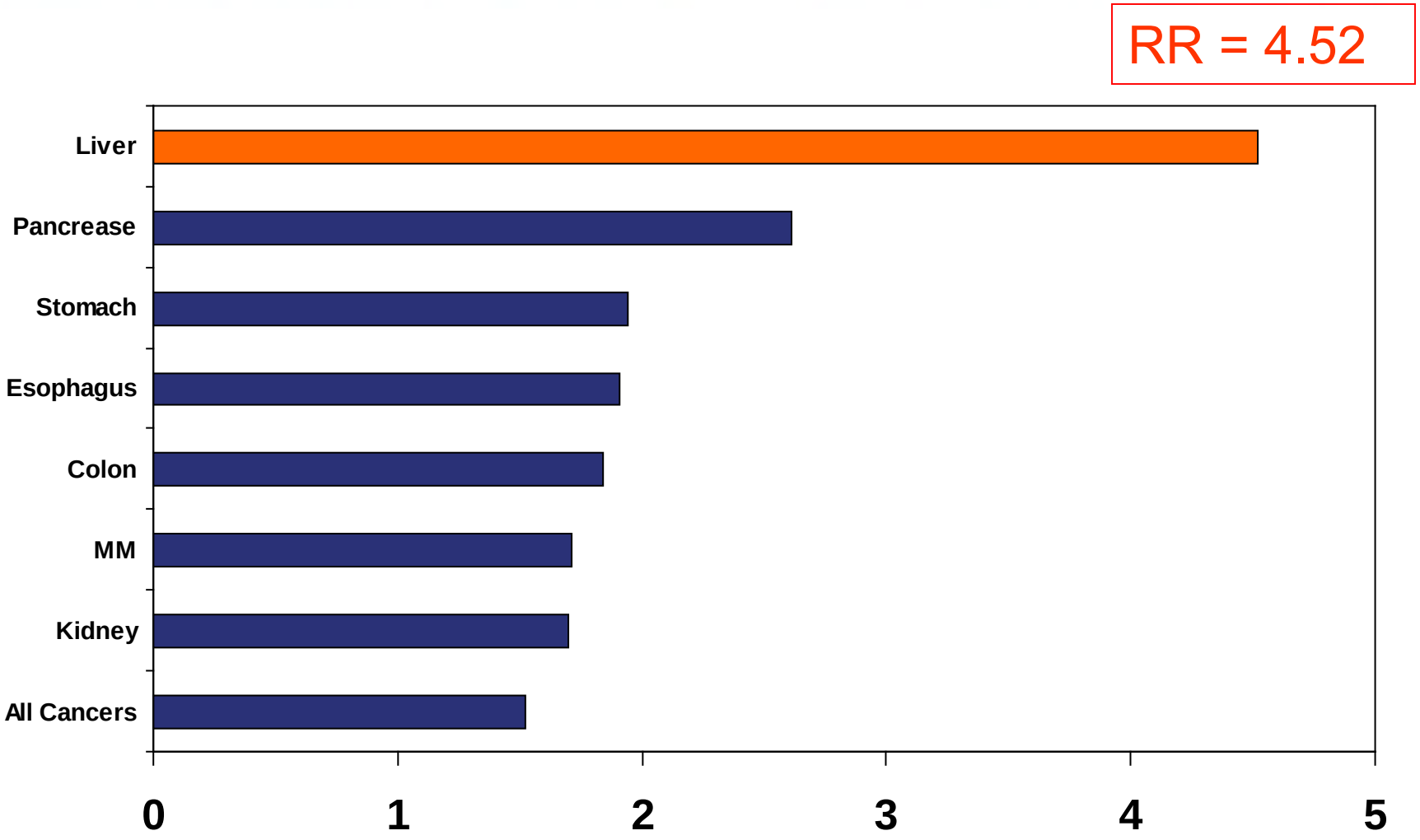
AASLD, IDSA, IAS
http://www.hcvguidelines.org. Accessed July 15, 2015.

Globesity



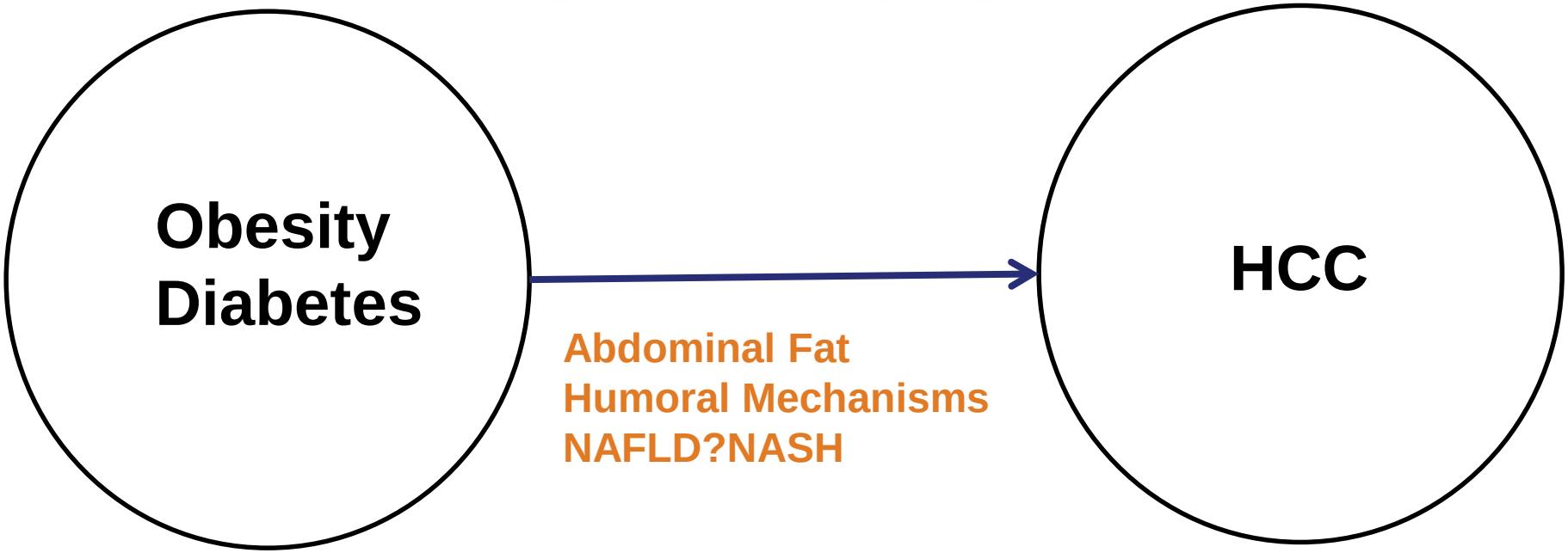
2006

Relative Risk of Malignancies in individuals with BMI ≥ 35 (compared to BMI < 25)



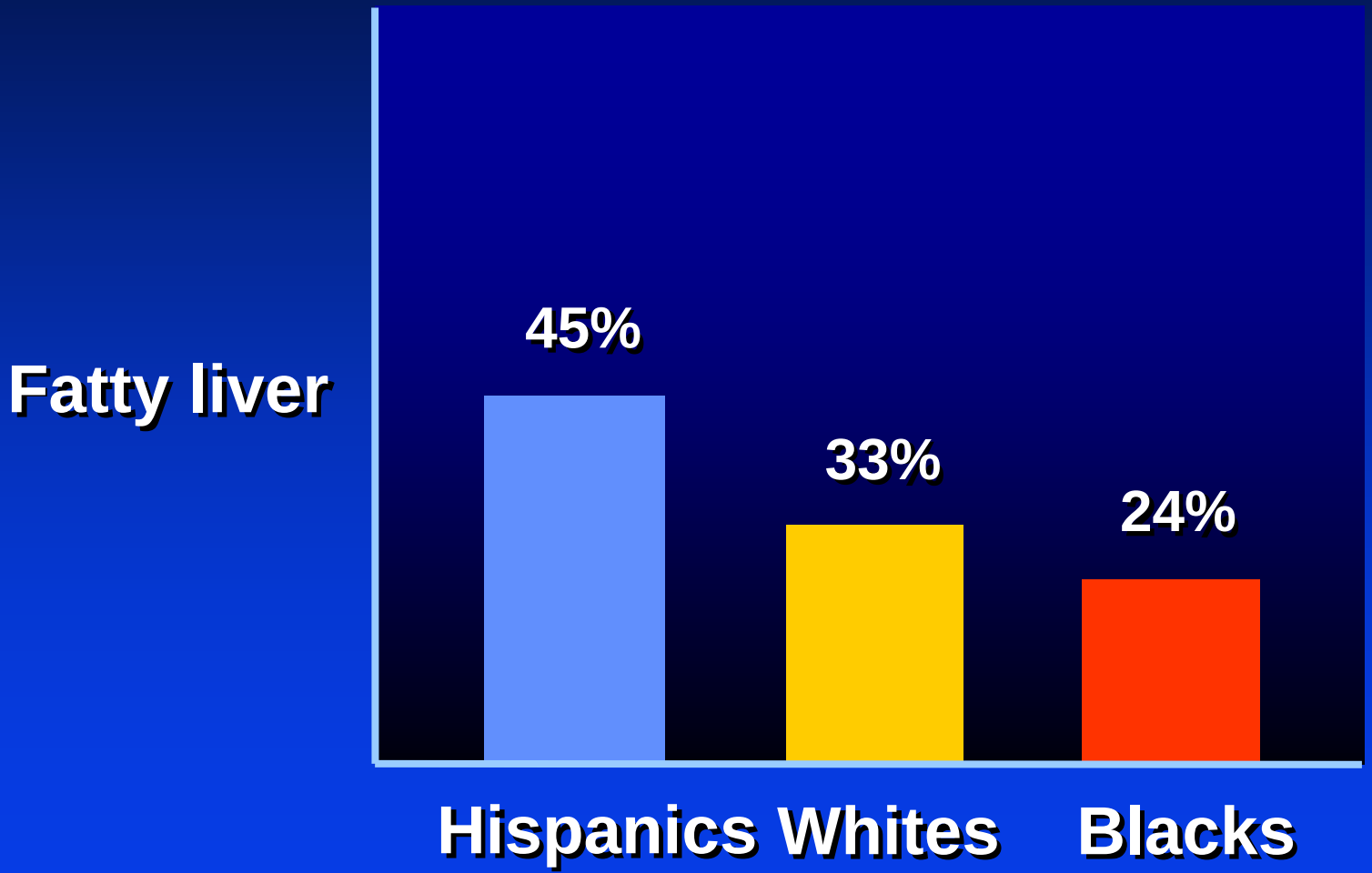
Calle EE, et al. NEJM 2003 (data basd on 900,000+ Men and Women)

Distal vs. Proximal Associations



- **Proximal** associations
  - Understand cancer pathogenesis in general
  - May help in diagnosis, prevention and treatment

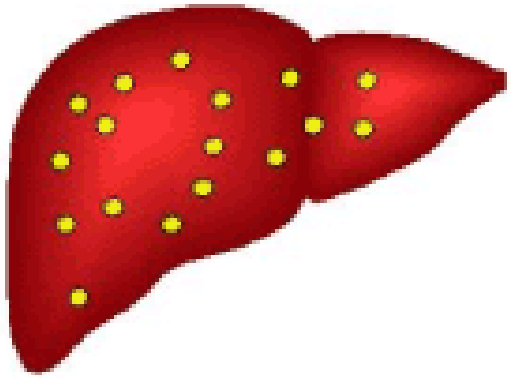
Prevalence of Hepatic Steatosis Varies with Ethnicity



Browning, et al., Hepatology 2004; 40:1387

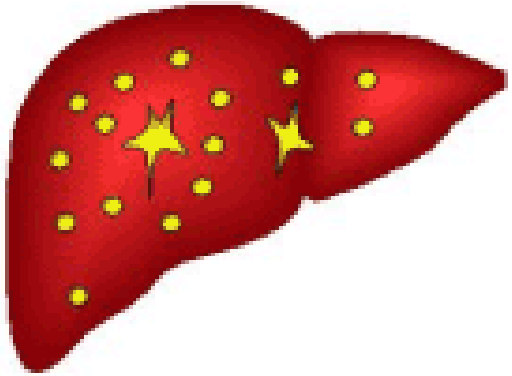
The Spectrum of NAFLD

Fatty Liver



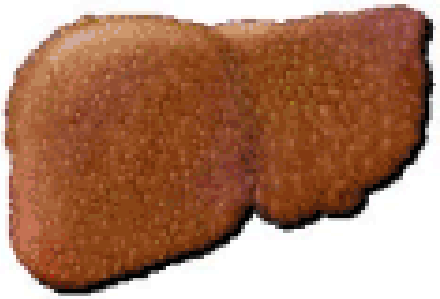
Steatosis

NASH



Fatty liver
+
inflammation
+
liver injury

Cirrhosis



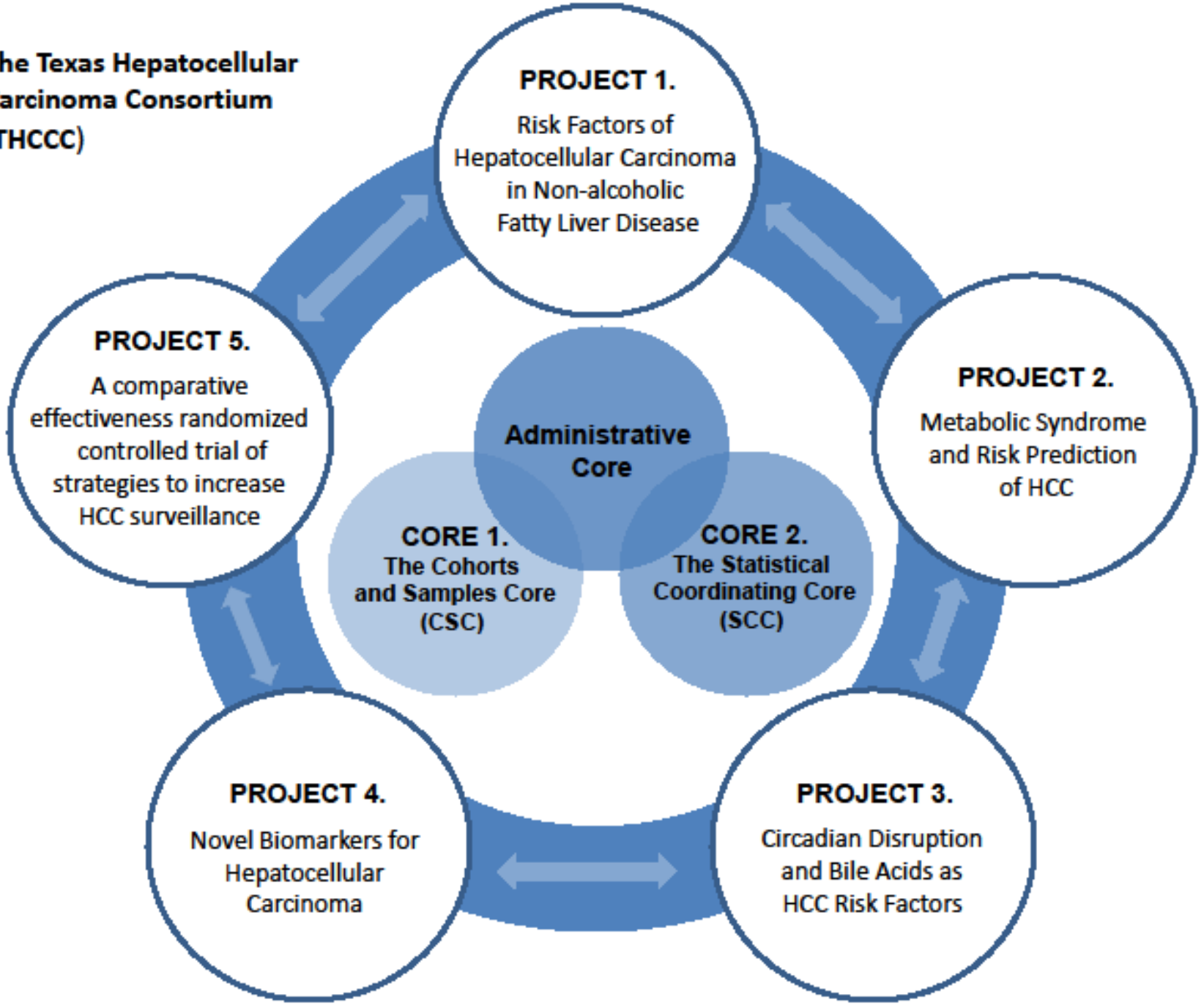
Fibrosis and nodular regeneration

CPRIT-MIRA (2015-2020)
Texas HCC Consortium
Overview of THCCC

Our overarching goal is to reduce the burden of HCC in Texas.

- multidisciplinary group of investigators with vast experience and expertise in HCC research.
- researchers from UT Southwestern Medical Center and Parkland Health and Hospital System in Dallas, Baylor College of Medicine and MD Anderson in Houston, and UT San Antonio
- inclusion of sites all across Texas to enrich the diversity and representativeness of our patients, ensuring a racially and ethnically diverse cohort
- critical gaps and needs in the HCC prevention process and appropriate ways to address them

The Texas Hepatocellular Carcinoma Consortium (THCCC)



Project 1: Risk Factors of Hepatocellular Carcinoma in Non-Alcoholic Fatty Liver Disease

(PI: Fasiha Kanwal)

Aim 1: To examine the risk of HCC in NAFLD patients in all Texas VA centers

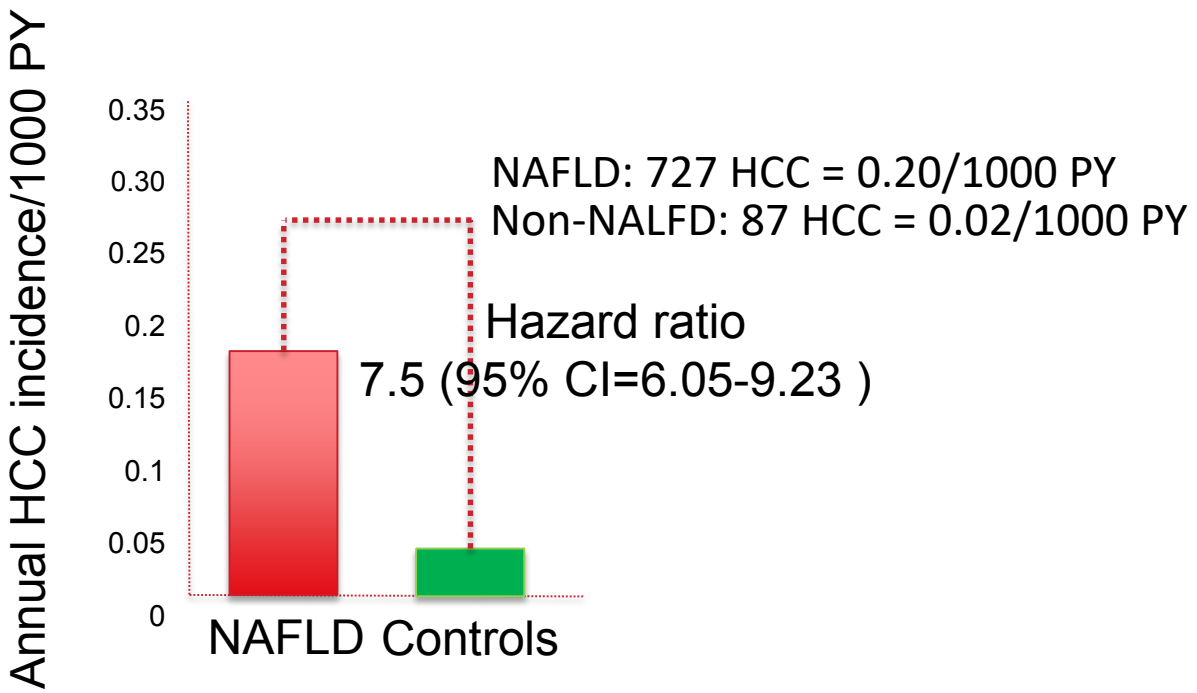
Aim 2: To identify predictors of HCC in NAFLD. We will assess the role of demographic (e.g., age, race) and metabolic traits (e.g., diabetes, obesity, dyslipidemia, hypertension diagnoses and biomarkers like hemoglobin A1c) in the development of HCC in NAFLD patients.

Aim 3: To determine the chemopreventive effect of common treatments in NAFLD including metformin and statins and the risk of HCC among patients with NAFLD.

HCC in Patients with (Biochemical) NAFLD

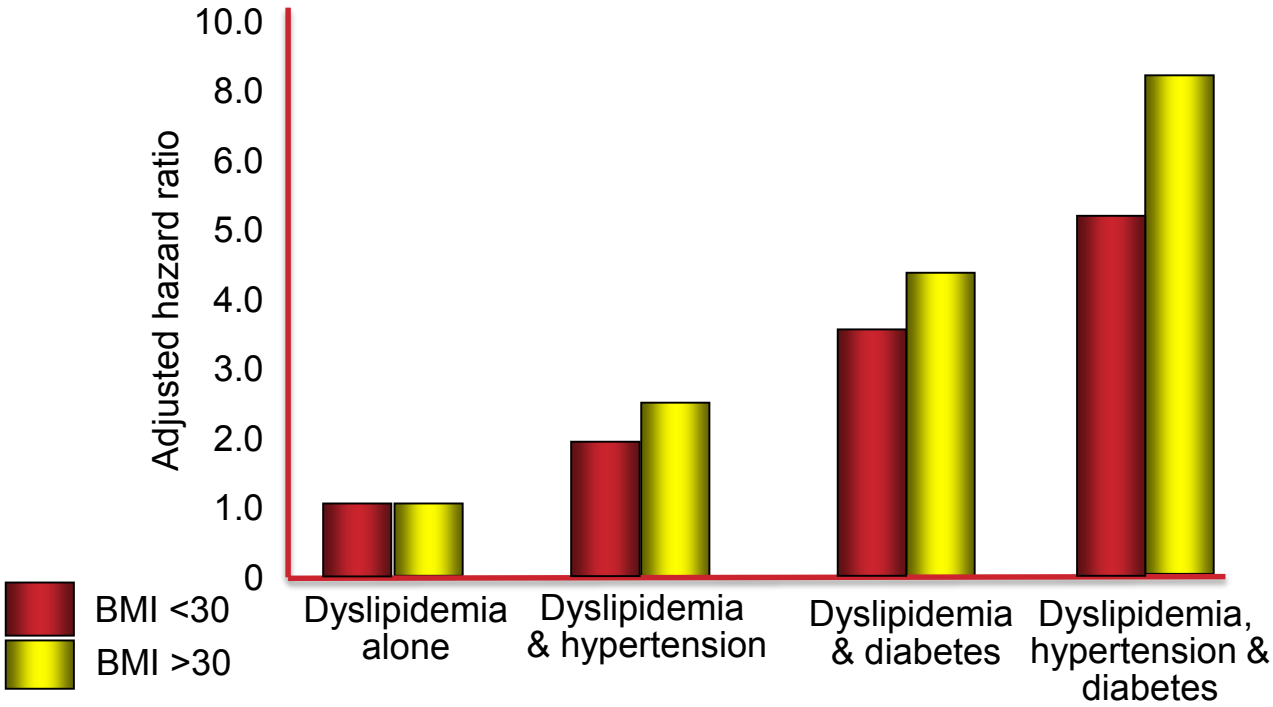
452,767 with NAFLD and 450,627 w/o NAFLD

Mean 9.1 (SD 2.9) year follow-up



Kanwal F et. al. Gastroenterology 2018

Effect of Metabolic Traits on NAFLD Progression to HCC



Kanwal F et. al. Gastroenterology 2018

Project 2: Metabolic Syndrome and HCC Risk Stratification in Patients with Cirrhosis

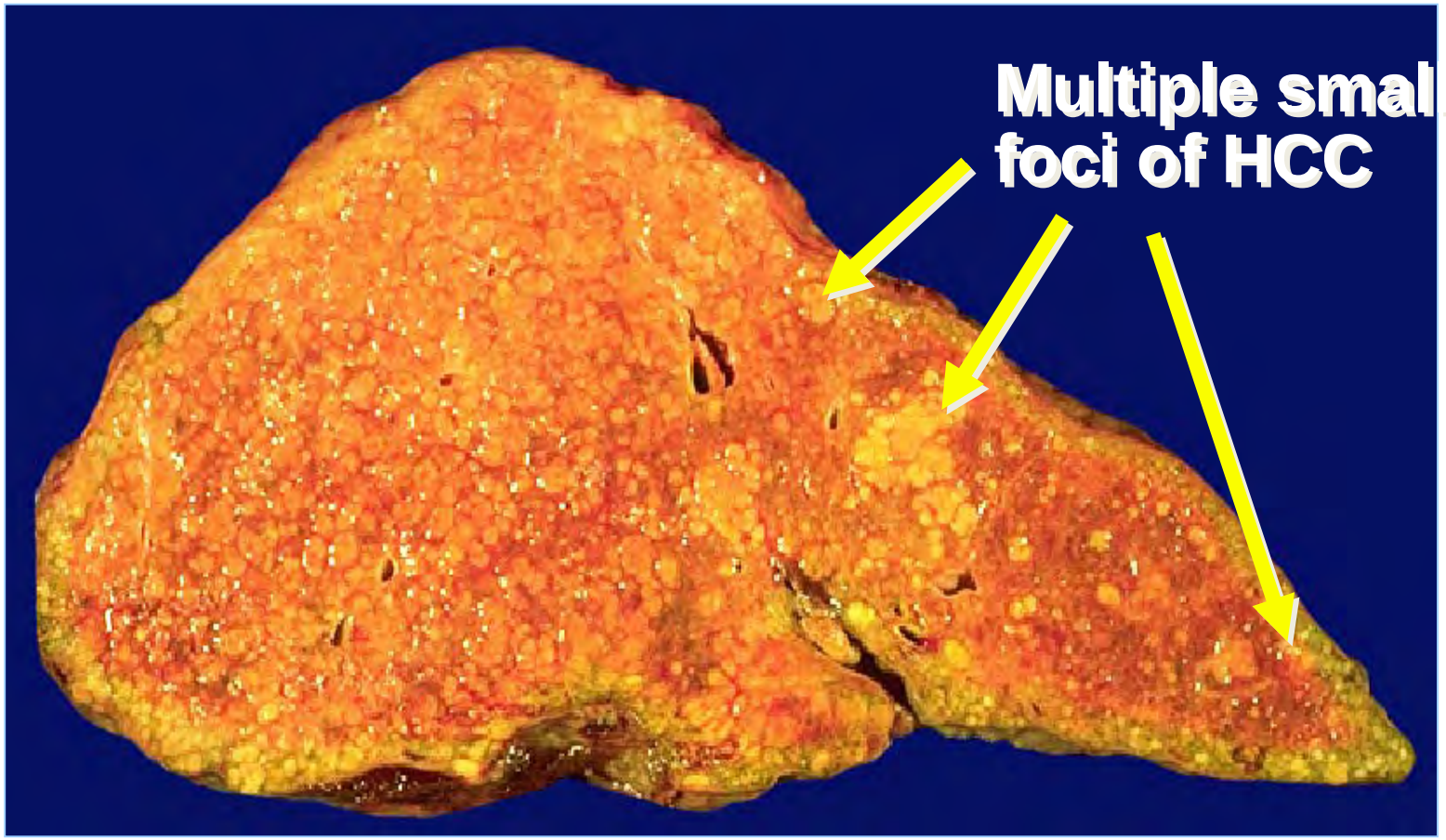
(PI: Hashem El-Serag)

Aim 1: Examine the Association between Metabolic Syndrome and HCC Risk in Cirrhosis.

Gross and molecular phenotype, genotype

Aim 2: Develop and optimize an index for predicting the risk of progression from cirrhosis to HCC using a set of candidate factors derived from the literature, Aim 1 or uncovered by other THCCC projects.

Hepatocellular Carcinoma (HCC) in a Liver with Cirrhosis



AJG The American Journal of GASTROENTEROLOGY

Design of the Texas Hepatocellular Carcinoma Consortium Cohort Study

Ziding Feng;Jorge Marrero;Saira Khaderi;Amit Singal;Fasiha Kanwal;Nicole Loo;Laura Beretta;Jing Ning;Hashem El-Serag. Jan 2019

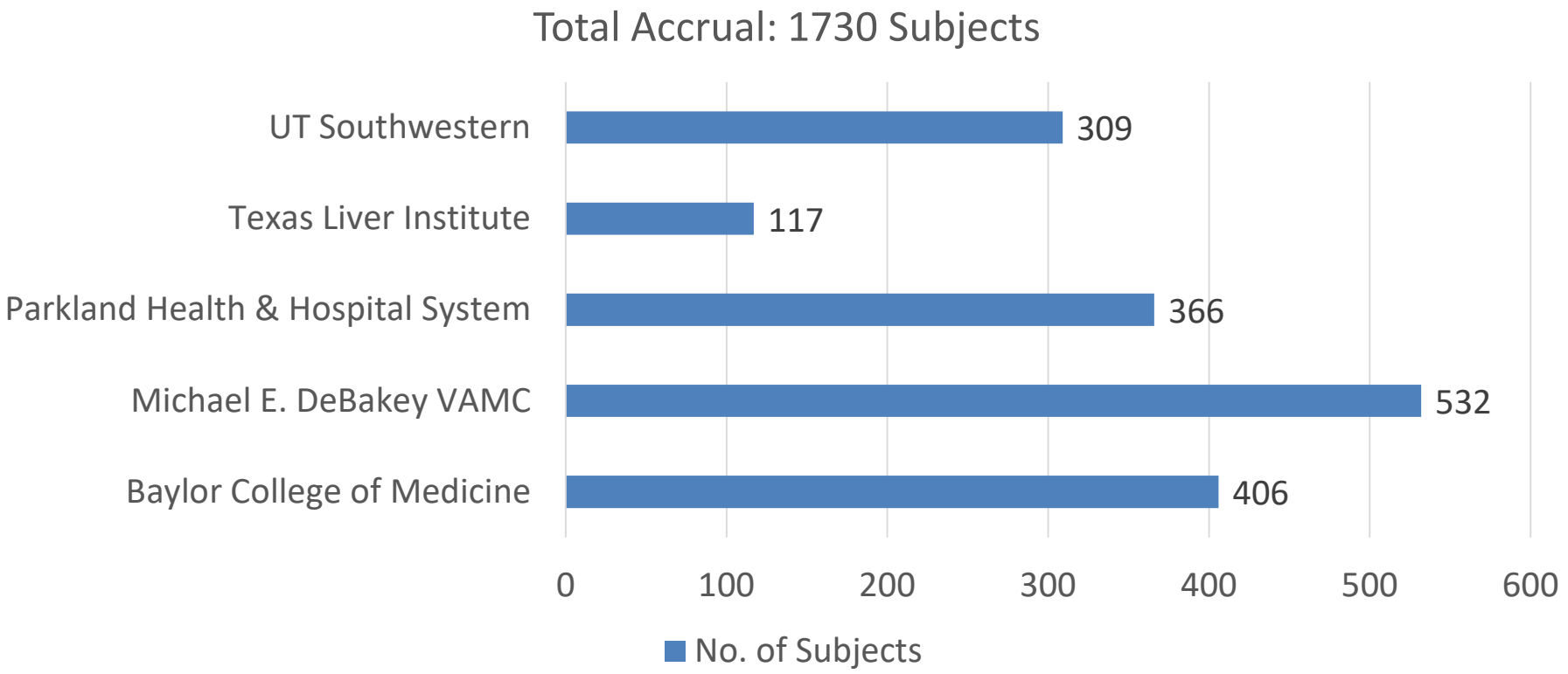
OBJECTIVES: The Texas Hepatocellular Carcinoma Consortium cohort study investigates risk factors of hepatocellular carcinoma (HCC) and biomarkers for early HCC detection in patients with liver cirrhosis.

METHODS: Adult patients with liver cirrhosis are enrolled at 5 clinical centers from 3 cities in Texas, with a target of 5,000 patients. Clinical history, risk factor questionnaires, liver imaging, laboratory data, and blood samples were collected at enrollment and at each 6-month follow-up visit.

RESULTS: The primary outcome was the development of HCC. Biomarkers were tested in banked blood samples using prospective specimen collection, retrospective blinded evaluation design.

CONCLUSIONS: We describe study design, eligibility criteria, recruitment, study cores, and sample size and analysis considerations.

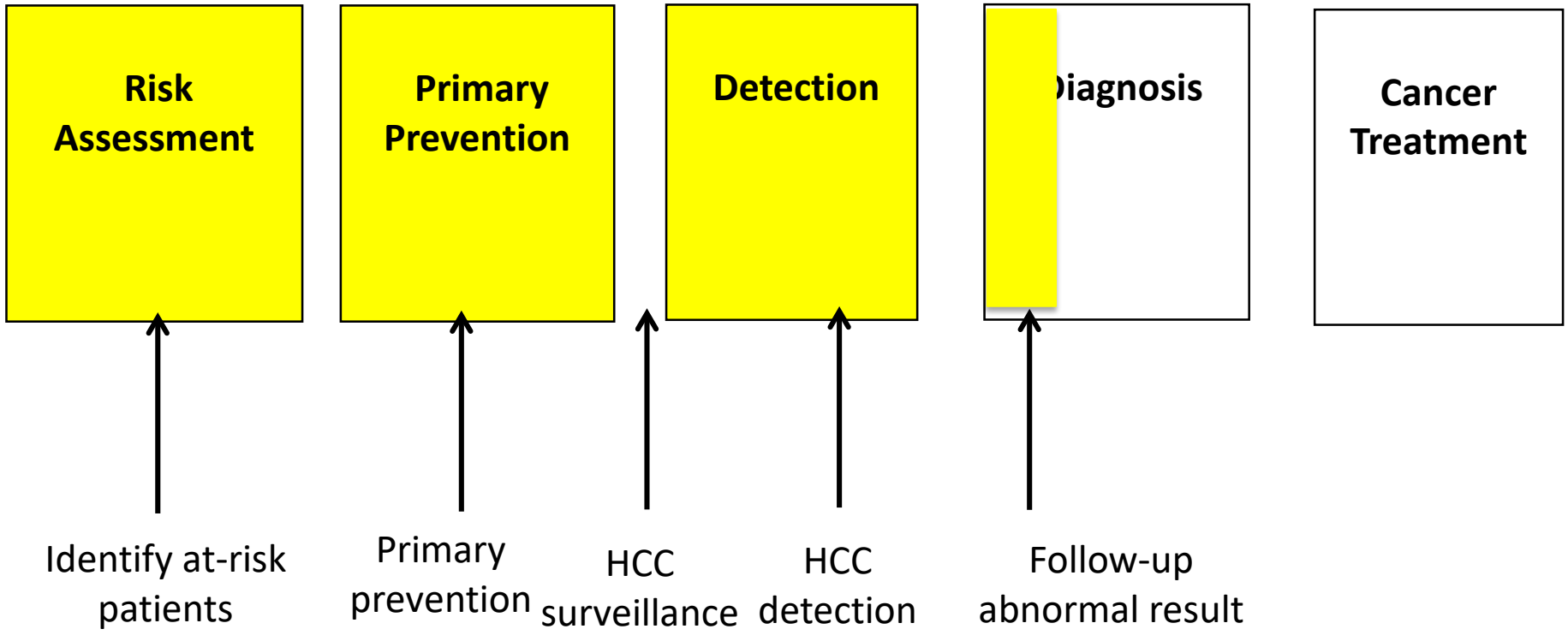
Accrual by Site as of 2/19/2019
Target 5000 (250-300 HCC)



Two additional sites Baylor University (Dallas) and Doctors Hospital (McAllen)
New U01 NIH grant

Texas HCC Consortium: First 1700 patients with cirrhosis

	White (N=847)	Black (N=368)	Hispanic (N=434)	Asian (N=24)	Others (N=22)
Male, N (%)	550 (65%)	290 (79%)	250 (58%)	14 (58%)	16 (73%)
BMI (sd)	36.2 (8.4)	34.1 (6.7)	39.8 (19)	30.1 (8.1)	35 (8.2)
Hep C Active, N (%)	113 (13%)	103 (28%)	57 (13%)	0 (0%)	5 (23%)
Hep C Resolved, N (%)	256 (30%)	187 (51%)	102 (24%)	6 (25%)	4 (18%)
Hep B, N (%)	35 (4%)	18 (5%)	8 (2%)	6 (25%)	2 (9%)
Alcoholic Liver Disease, N (%)	237 (28%)	108 (29%)	150 (35%)	4 (17%)	10 (45%)


Risk Assessment
Primary Prevention
Detection
Diagnosis
Cancer Treatment
Identify at-risk patients
Primary prevention
HCC surveillance
HCC detection
Follow-up abnormal result

Summary

- HCC is an important killer that afflicts many Texans.
- Prevention of HCC is the main step to reduce death and suffering.
- Understanding risk factors for HCC is essential for prevention.
- CPRIT has provided an unrivaled opportunity for research and prevention of HCC through creation of THCCC
- More needs to be done!

Hashem B El-Serag, MD, MPH

Margaret M and Albert B Alkek Professor and Chair
Department of Medicine
Director of the Texas Digestive Disease Center
Baylor College of Medicine
Houston, TX

Hashem B El-Serag, MD, MPH, is the Chairman of the Margaret M. and Albert B. Alkek Department of Medicine and Director of the NIH funded Texas Digestive Disease Center at Baylor College of Medicine in Houston, TX. He received his medical degree from Al-Arab Medical University in Libya, completed his residency in Internal Medicine at Greenwich Hospital, Yale University, and completed a fellowship in Clinical Gastroenterology at the University of New Mexico, Albuquerque, where he also earned his master's degree in public health. His research focuses on the clinical epidemiology and outcomes of several liver disorders, including GERD, Barrett's esophagus, hepatocellular carcinoma, and hepatitis C. Dr El-Serag has over 400 articles published in notable academic journals, such as The New England Journal of Medicine, Annals of Internal Medicine, Archives of Internal Medicine, Gastroenterology, and Hepatology. He has assumed several leadership roles in national organizations including the American Gastroenterological Association, American College of Gastroenterology, and American Association for the Study of Liver Diseases, and is a member of the American Society for Clinical Investigators and Association of American Physicians.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

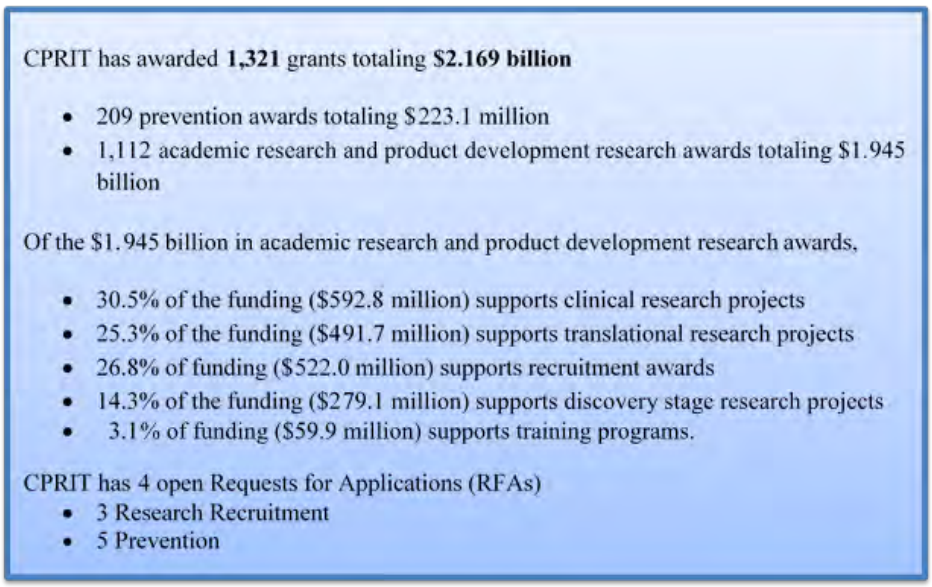
TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	WAYNE ROBERTS, CHIEF EXECUTIVE OFFICER
SUBJECT:	AGENDA ITEM 6, CHIEF EXECUTIVE OFFICER REPORT
DATE:	FEBRUARY 11, 2019

As of this writing the Chief Executive Officer's Report for the February 21, 2019, Oversight Committee meeting will consist of the following items:

- Personnel update-introduction of Chief Product Development Officer
- *CPRIT 2018 Annual Report*
- New CPRIT Website
- Status of legislation affecting CPRIT
    - Senate Bill 1/House Bill 1 (General Appropriations Act)
    - General Legislation
- FY 2019 Grant Award Funds Available (attached)

Other topics may be added as warranted.

In addition, for your reference copies of the December 2018 and January 2019 CPRIT Activities Updates previously provided to you are included at the end of this tab. These reports are done in months in which the Oversight Committee does not meet.



CPRIT MANAGEMENT DASHBOARD
FISCAL YEAR 2019

	SEPT	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	CUMULATIVE (ANNUAL)	CUMULATIVE (TO DATE)
ACCOUNTABILITY														
Announced Grant Awards			4										4	
New Grant Contracts Signed	3	29	11	2	9								54	
New Grant Contracts In Negotiation			12										12	
Grant Reimbursements Processed (#)	215	155	151	117	135								773	
Grant Reimbursements Processed ($)	$ 24,200,640	$ 35,131,951	$ 8,541,059	$ 11,659,905	$ 15,228,234								$ 94,761,789	
Revenue Sharing Payments Received	$ -	$ -	$ 158,052	$ -	$ 15,000								$ 173,052	$ 3,594,605
Total Value of Grants Contracted ($)	$ 21,386,494	$ 63,467,857	$35,654,020	$ 2,200,000	$ 18,649,550								$ 141,357,921	
Grants Awarded (#)/ Applications Rec'd (#)	13%	13%	13%	13%	13%									
Debt Issued ($)/Funding Awarded ($)	74%	74%	73%	73%	73%									
Grantee Compliance Trainings	3	1	2	2	1								9	
Grantee Compliance Monitoring Visits	0	3	0	3	2								8	
Awards with Delinquent Reimbursement Submission (FSR)			0											
Awards with Delinquent Matching Funds Verification			0											
Awards with Delinquent Progress Report Submission			2											
IA Agency Operational Recommendations Implemented	0	0	0	0	0									
IA Agency Operational Recommendations In Progress	9	9	9	9	9									
Open RFAs	10	9	12	16	15									
Prevention Applications Received	19	0	0	2	0								21	816
Product Development Applications Received	0	0	0	0	28								28	491
Academic Research Applications Received	7	2	2	5	168								184	6,862
Help Desk Calls/Emails	111	131	83	138	270								733	
MISSION														
ACADEMIC RESEARCH PROGRAM														
Number of Research Grants Announced (Annual)	0		4										4	
Recruited Scientists Announced														226
Recruited Scientists Accepted														170
Recruited Scientists Contracted	`													160
Published Articles on CPRIT-Funded Projects (#)														
Jobs Created & Maintained (#)														
Trainees in CPRIT-Funded Training Programs (#)														
Clinical Studies (#)														109

CPRIT MANAGEMENT DASHBOARD
FISCAL YEAR 2019

	SEPT	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	CUMULATIVE (ANNUAL)	CUMULATIVE (TO DATE)
Number of Patents Resulting from Research														
Number of Patent Applications														
Number of Investigational New Drugs														
PRODUCT DEVELOPMENT RESEARCH PROGRAM														
Number of Product Development Grant Announced (Annual)			0										0	
Life Science Companies Recruited (in TX)														9
Published Articles on CPRIT-Funded Projects														
Number of Jobs Created & Maintained														515
Clinical Trials (#)														15
Number of Patents Resulting from Research														
Number of Patent Applications														
Number of Investigational New Drugs														
PREVENTION PROGRAM														
Number of Prevention Grants Announced (Annual)			0										0	
People Served by CPRIT-Funded Prevention and Control Activities			223,464										223,464	
People Served through CPRIT-Funded Education and Training			136,707										136,707	
People Served through CPRIT-Funded Clinical Services			86,757										86,757	
TRANSPARENCY														
Total Website Hits (Sessions)	6,200	6,300	5,300	4,900	8,700								31,400	
Total Unique Visitors to Website (Users)	4,700	4,700	3,900	3,500	6,100								22,900	

FY 2019 GRANT AWARD FUNDS AVAILABLE

General Obligation Bond Proceeds

	Prevention	Academic / Product Development Research	1% Grant Funding Buffer	Operating Budget	Total Appropriations
Available Appropriated Funds	$ 28,022,956	$ 255,297,292		$ 16,679,752	$ 300,000,000
Approved Adjustment to Operating Budget		$ (547,031)		$ 547,031	
Appropriations Transfer to DSHS		$ (2,969,554)		$ 2,969,554	
Adjusted Appropriations	$ 28,022,956	$ 251,780,707		$ 20,196,337	$ 300,000,000
Total Available for All Grants			$ 279,803,663		
1% of Total Available Grant Funding			$ 2,798,037		
Adjusted Grant Award Funding	28,022,956	$ 248,982,670			$ 277,005,626

	Prevention Grants	Academic Research Grants	PD Research Grants		
Total Available for Grant Awards (Total GO Bond Proceeds Less Operating Budget)	$ 28,022,956	$ 176,246,495	$ 75,534,212		$ 279,803,663
Total Available for Grant Awards Incorporating 1% Grant Funding Buffer	$ 28,022,956	$ 174,287,869	$ 74,694,801		$ 277,005,626
Announced Grant Awards					
11/28/18 AR Recruitment Awards (4)	$ -	$ 16,000,000	$ -		
Announced Grant Award Subtotal	$ -	$ 16,000,000	$ -	$ -	$ 16,000,000
Grant Award Adjustments					
Declined Recruit Award (BCM-Satpathy) 11/2018 Slate	$ -	$ (2,000,000)	$ -		$ (2,000,000)
Revised Grant Award Subtotal	$ -	$ 14,000,000	$ -		$ 14,000,000
Available Funds as of February 1, 2019	$ 28,022,956	$ 160,287,869	$ 74,694,801		$ 263,005,626
Pending Grants-PIC Recommendations					
IIR Awards (23)	$ -	$ 20,623,861	$ -		
IIRA-Childhood and Adolescent Cancer (5)	$ -	$ 5,968,636	$ -		
IIRA-Computational Biology (1)	$ -	$ 885,185	$ -		
IIRA-Clinical Translation (4)	$ -	$ 7,488,820	$ -		
IIRA-Prevention and Early Detection (3)	$ -	$ 3,890,151	$ -		
Recruitment Awards (6)	$ -	$ 14,000,000	$ -		
PDR Relocation Award	$ -	$ -	$ 13,116,095		
PDR SEED Awards (3)	$ -	$ -	$ 8,912,313		
PDR Texas Company Award	$ -	$ -	$ 8,742,509		
Prevention Awards	$ 12,328,462	$ -	$ -		
Pending Award Subtotal	$ 12,328,462	$ 52,856,653	$ 30,770,917		$ 95,956,032
Revised Available Grant Funds	$ 15,694,494	$ 107,431,216	$ 43,923,884		
Total Potential Grant Funding Committed	$ 12,328,462	$ 66,856,653	$ 30,770,917		$ 109,956,032
Available Funds as of February 7, 2019	$ 15,694,494	$ 107,431,216	$ 43,923,884		$ 167,049,594
1% Grant Funding Buffer	$ -	$ 1,958,626	$ 839,411		$ 2,798,037

Operating Budget Detail		
Indirect Administration	$ 3,577,683	
Grant Review & Award Operations	$ 13,649,100	
Subtotal, CPRIT Operating Costs	$ 17,226,783	
Cancer Registry Operating Cost Transfer	$ 2,969,554	
Total, Operating Costs	20,196,337	

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	WAYNE R. ROBERTS, CHIEF EXECUTIVE OFFICER
SUBJECT:	CPRIT ACTIVITIES UPDATE DECEMBER 2018
DATE:	JANUARY 3, 2019

Topics in this memo cover the month of December 2018 and include recent milestones in our fight against cancer, a staffing summary, CPRIT outreach efforts, CPRIT's legislative session preparation, and updates from Compliance, Programs, and Operations.

Recent Milestones in the Fight Against Cancer

CPRIT Grantees in the News

- The Gordon and Betty Moore Foundation announced in November that CPRIT grantee, Dr. Livia Eberlin, assistant professor in the Department of Chemistry at The University of Texas at Austin, is one of this year's five Moore Inventor Fellows. The fellowship program recognizes distinguished early-career innovators at universities across the U.S. and supports research efforts that have a high potential to accelerate progress in science and patient care. Fellows receive $825,000 each over three years to drive their inventions forward. This fellowship is just the latest in a string of honors for Dr. Eberlin. In 2018 alone, she received a prestigious MacArthur Foundation Fellowship, won the Interactive Innovation Award at SXSW and was named UT Austin's Emerging Inventor of the Year. Dr. Eberlin's CPRIT funded research is evaluating the cancer-detecting MassSpec Pen in thyroid (RP170427), lung (RP160776), and ovarian cancers (RP180381).

- On November 20, the Pancreatic Cancer Collective, a partnership of the Lustgarten Foundation and Stand Up To Cancer, awarded $1 million to a team headed by Dr. Patrick Hwu, The University of Texas MD Anderson Cancer Center, to create tumor-specific killer T cells (tumor-infiltrating lymphocytes, or "TILs") that are resistant to transforming growth factor beta (a protein that can counteract the immune system), and use the TILs to attack pancreatic cancer. This project builds on CPRIT-funded research (RP110553) to create TIL cells resistant to immune surveillance. Pending the results of preliminary studies, Dr. Hwu's team will be eligible for an additional $4 million to support clinical trials in patients with pancreatic cancer.

- CPRIT grantee, Dr. Ralph DeBerardinis, Professor of Pediatrics, The University of Texas Southwestern Medical Center will receive the 2019 O'Donnell Award from The Academy of Medicine, Engineering and Science of Texas (TAMEST) January 15 at TAMEST's annual

PO Box 12097 | Austin, Texas 78711 | PH: 512-463-3190 | F: 512-475-2563 | cprit.texas.gov

meeting in Horseshoe Bay, Texas. The O'Donnell Award includes a $25,000 honorarium and recognizes outstanding achievements by Texas early career investigators. Dr. DeBerardinis' work, which was initiated by his CPRIT grants (RP100437, RP130272, RP140021, and RP160089), includes pioneering a new way to study altered metabolism in cancer patients.

- Immatics Biotechnologies GmbH, the parent company of CPRIT grantee Immatics US Inc., is leading the Glioma Actively Personalized Vaccine Consortium (GAPVAC) that is progressing GAPVAC-101 through its first-in-human clinical trial testing a novel therapeutic concept tailored to specific characteristics of patients' individual tumors and immune systems. GAPVAC reported data from the phase 1 study of GAPVAC-101 in *Nature*. According to the company, this is the first time the feasibility of such a highly personalized form of immunotherapy has been exemplified in a multi-center, multi-national clinical setting.

  The GAPVAC-101 trial served as a blueprint for Immatics US's ACTolog IMA101-101 trial. Immatics is currently running the CPRIT-funded ACTolog® IMA101 clinical trial at MD Anderson Cancer Center. ACTolog is the first adoptive cell therapy trial applying the concept of active personalization. The ACTolog IMA101 and GAPVAC-101 trials address tumors like glioblastoma that have not benefited from recent breakthroughs with checkpoint inhibitors due to low mutational load. Many tumor types have a low mutational load with only a few neoantigens targetable by the immune system. These cancers represent a high unmet medical need and require additional therapeutic strategies tailored to the features of the patient's individual tumor. Immatics US received a $19.6 million CPRIT Product Development Award in 2015, which provided support for the ACTolog IMA101 development and clinical trials.

Notable CPRIT Supported Research Accomplishments

- CPRIT funded research (RP140594) led by Manjeet Rao, Ph.D., associate professor of cell systems and anatomy at UT Health San Antonio and a member of the Greehey Children's Cancer Research Institute, found a molecule able to kill medulloblastoma, the most common childhood brain cancer. The molecule under study sensitizes cancer to chemotherapy and radiation, making it plausible to treat tumors with one-tenth the dose required currently. *Nature Communications* reported Dr. Rao's research.

- CPRIT Scholar Dr. Kathryn O'Donnell, Assistant Professor of Molecular Biology at UT Southwestern, has discovered an enzyme on the surface of some lung cancer cells that helps feed the cancer, making it a tempting treatment target. A report published in the journal *Cell Reports* describes the enzyme, transmembrane serine protease 11B (TMPRSS11B). Her team identified TMPRSS11B while searching for genes that can convert precancerous lung cells into malignant cells that can form tumors. Because most healthy cells appear to lack TMPRSS11B, it is the perfect cancer drug target - it is accessible on the tumor cell surface, it is selective for cancer cells, blocking it both inhibits the cancer growth and sets the stage for developing better immunity against the cancer, and its presence makes it a diagnostic.

- OncoNano Medicine, Inc. announced the end of a Phase 1a clinical trial and expansion into Phase 1b to evaluate ONM-100, an intravenously administered imaging agent to detect tumors and metastatic lymph nodes in solid cancers during surgery. The company disclosed Phase 1a trial results in a poster presentation at the San Antonio Breast Cancer Symposium in early December. OncoNano received a $6 million CPRIT Product Development Award in August 2014, which provided support for the development of ONM-100.

  Surgery is the standard treatment for most solid tumors, with postoperative margin status and tumors left behind being the leading prognostic factor to predict tumor metastasis and potential recurrence. Despite tremendous advances in imaging modalities, current techniques do not provide real-time feedback and surgeons must rely upon pre-operative imaging data and what they observe during surgery. ONM-100 targets the acidic pH environment within tumors, providing surgeons with a method to assess lymph nodes and tumor margins in real-time. ONM-100 features a digital on-off response to pH changes – switching on in the tumor's acidic environment and remaining off in blood circulation and normal cells.

  Dr. Ravi Srinivasan, founder, President, and Chief Executive Officer of OncoNano, said, "We are buoyed by the results of Phase 1a where tumors were detected that had previously been undetected by standard of care preoperative methods and by the surgeon or the pathologist, and we look forward to continuing this important trial."

- Cell Medica presented data from the company's CITADEL study at the Society for Immunotherapy of Cancer 2018 Conference. Cell Medica reported early results from a Phase 2 study (CITADEL, NCT01948180) of autologous EBV-specific cells for the treatment of advanced NK/T-cell lymphoma (NKTL). Cell Medica received a $15.6 million CPRIT Product Development Award in March 2012 that supported the CITADEL trial.

  NKTL is a rare, aggressive lymphoma. The company conducted the CITADEL study in the U.S. (including two sites in Texas), France, South Korea, and the UK. The 15-patient study demonstrated feasibility, clinical activity, and safety of administration of single agent autologous EBV-specific T cells in patients with relapsed NKTL in a multicenter, multinational trial. Cell Medica is planning to perform validation in a larger cohort.

Personnel

CPRIT has filled 34 of its 35 authorized full-time equivalent (FTE) positions. Interviews for the vacant Chief Product Development Officer have concluded; CPRIT expects an announcement concerning the successful candidate in early January.

CPRIT Outreach

- Kristen Doyle, Deputy Executive Officer and General Counsel, Heidi McConnell, Chief Operating Office, and I met with Comptroller Glenn Hegar and members of his staff on November 28 to discuss use of funds to support CPRIT research and plans for the 86th Texas Legislature that begins January 8, 2019.

- On November 30 CPRIT Chief Scientific Officer Dr. James Willson, Senior Program Manager for Academic Research Dr. Patty Moore, Chief Prevention and Communications Officer Dr. Rebecca Garcia, Ms. Doyle, and I met with Dr. Larry Schlesinger, President & CEO of the Texas Biomedical Research Institute in San Antonio, to discuss his concept paper for a cancer and infectious disease research center of excellence.

- I was a panelist at the HealthTech Austin Medical Device Summit on December 6, discussing partnering with large entities.

- I met with staff of Representative Dennis Bonnen, the presumed next Speaker of the House of Representatives, on December 17 to discuss CPRIT-related issues for the 86th Texas Legislature.

- Ms. Doyle, Ms. McConnell, Dr. Garcia, Chris Cutrone, CPRIT Senior Communications Specialist, and I met with members of the Texas Cancer Partnership on December 18 to discuss CPRIT's plans for the 86th Texas Legislature.

- On December 19 Ms. Doyle and Rosemary French, Senior Program Manager for Product Development, hosted a webinar for potential Product Development Program grant applicants. Three Product Development Program peer reviewers also took questions from the webinar participants. We have posted the webinar and the questions answered on CPRIT's website.

The Perryman Group Highlights CPRIT in its December Special Report

In its December 21st edition of the *Perryman Report and Texas Letter*, the Perryman Group highlighted key results of its recent analysis of CPRIT's economic impact. The group has measured CPRIT's economic benefits for several years and reports that the agency generates hundreds of millions of dollars in additional business activity each year and substantial additional taxes for state and local governments. The group also analyzed the effect on Texas if CPRIT's programs end, reporting that the net cumulative economic losses over the additional 10 years not being funded remain substantial even when considering other potential uses for state funding of CPRIT. These net losses include $141.7 billion in lost gross product and some 1.2 million lost person-years of employment. *CPRIT's 2018 Annual Report*, which will be issued by January 31, 2019, will include the Perryman Group's economic analysis.

Compliance Program Update

Submission Status of Required Grant Recipient Reports

CPRIT's grants management system (CGMS) produces a summary of delinquent reports each week; this is the primary source used by CPRIT's compliance staff to follow up with grantees. CPRIT typically has 560+ grants that are either active or wrapping up grant activities and receives an average of 560 grantee reports each month.

As of November 30, 2018, one entity had not filed two Academic Research reports by the due date. However, as of December 17, 2018, nine entities had not filed 108 reports by the due date. Over 90% of these delinquent reports were from one grantee and most of these reports are in a

30-day grace period as established by CPRIT's administrative rules. The grantee reported to CPRIT that they recently experienced staff turnover and plan to submit all delinquent reports by December 29, 2018, which is the end of the grace period.

CPRIT's grant accountants and compliance specialists review and process incoming reports and reach out to grantees to resolve filing issues. In most cases, CPRIT does not disburse grant funds until the grantee files the required reports. In some instances, grantee institutions may be ineligible to receive a future award if the grantee does not submit the required reports.

Financial Status Report Reviews

CPRIT's Compliance Specialists performed about 235 second-level reviews of grantee Financial Status Reports (FSRs) during the months of November and December. Ten FSRs (6%) required resubmission due to insufficient or inaccurate documentation submitted by the grantee. For the first quarter of FY 2019, Compliance Specialists completed 515 second-level reviews. CPRIT's grant accounting staff completes the initial review of FSRs and supporting documentation before routing them to the compliance specialists for final review and disposition.

Single Audit Tracking

Compliance Specialists track the submission of grantees' independent audit reports and the resolution of issues identified in these reports. Grantees who expend $750,000 or more in state awards in the grantee's fiscal year must submit a single independent audit, a program specific audit, or an agreed upon procedures engagement. The grantee submits the independent audit report with audit findings to CPRIT within 30 days of receipt, but no later than 9 months after the grantee's fiscal year end.

Compliance Specialists are working with one grantee to remediate audit findings. CPRIT gives grantees 30 days from the receipt of the audit to submit supporting documentation to demonstrate remediation efforts. Currently, there is one grantee with a delinquent audit. Grantees are unable to receive reimbursements or advances if they are delinquent in filing the required audit and corrective action plan unless the grantee requested additional time by the due date of the required audit and CPRIT's CEO approved the request.

Desk Reviews

Compliance Specialists performed 42 desk-based financial monitoring reviews during the months of November and December. Desk reviews verify that grantees expend funds in compliance with specific grant requirements and guidelines and may also target an organization's internal controls, current and past fiscal audits, and timeliness of required grantee report submission. Compliance Specialists are working with three grantees to remediate desk review findings.

On-Site Reviews

Compliance Specialists conducted three on-site reviews during December. On-site reviews examine the grantee's financial and administrative operations, subcontract monitoring, procurement and contracting procedures, inventory procedures, personnel policies and procedures, payroll and timesheet policies, travel policies and records, and single audit

compliance. Compliance Specialists are working with five grantees to remediate on-site review findings.

Training and Support

CPRIT staff conducted three new Authorized Signing Official (ASO) trainings during the months of November and December. The trainings covered grant reporting requirements, administrative rule changes, grant closeout, a hands-on navigation of CPRIT's grants management system, and an overview of the compliance program including fraud, waste, and abuse reporting. Pursuant to Texas Administrative Code §703.22, CPRIT requires new ASOs to complete a compliance training within 60 days of the change.

CPRIT staff also facilitated a grantee training on December 18 with the Baylor College of Medicine financial accounting team. This training provided targeted technical assistance related to financial status reporting and required support documentation for CPRIT grants.

Academic Research Program Update

FY 2019 Cycle 1 (19.1) RFAs Update

Applicants submitted nearly 400 proposals for FY 2019 Cycle 1 (19.1) grant awards. CPRIT conducted peer review October 18 – October 25 in Dallas. Dr. Willson plans to present the Scientific Review Council's (SRC) award recommendations to the Program Integration Committee (PIC) and the Oversight Committee in February.

Table 1: FY 2019.1 (19.1) Application Data by Mechanism

Mechanism	Rec'd	Funds Requested	In Full Review	Funds Requested	Rec'd by SRC	SRC Funds Rec'd
Individual Investigator Research Award (IIRA)	261	$233,976,917	144	$126,157,080	29	$26,021,344
IIRA for Cancer in Children and Adolescents	35	$44,382,130	24	$29,026,405	7	$7,889,942
IIRA for Clinical Translation	33	$52,321,758	23	$37,874,514	5	$9,576,748
IIRA for Computational Biology	25	$20,580,933	12	$9,544,680	3	$2,677,342
IIRA for Prevention and Early Detection	35	$34,294,805	26	$26,970,288	3	$3,890,151
TOTAL	**389**	**$385,556,543**	**229**	**$229,572,967**	**47**	**$50,055,527**

Recruitment Summary Data

CPRIT received four recruitment applications during recruitment cycles 19.4 and 19.5. Dr. Willson will present the SRC's award recommendations to the PIC and the Oversight Committee in February.

Table 2: FY 2019 Recruitment RFA data by Mechanism for Cycles 19.4 and 19.5

Mechanism	Received	Funds Requested	Rec'd by SRC	Funds Requested
Recruitment Established Investigators	0	0	0	0
Recruitment Rising Stars	0	0	0	0
Recruitment of First-Time Tenure Track Faculty Members	4	$8,000,000	3	$6,000,000
TOTAL	**4**	**$8,000,000**	**3**	**$6,000,000**

FY 2019 Cycle 2 Academic Research RFAs

The Oversight Committee approved a second cycle of 2019 RFAs in February 2018. CPRIT released the RFAs (described below) on August 17 and will receive applications from October 17, 2018, through January 30, 2019. CPRIT will convene the peer review panels in May. Dr. Willson will present the SRC's recommendations to the PIC and Oversight Committee in August 2019.

- *Core Facility Support Awards (CFSA) (RFA R-19.2 CFSA)*
  Solicits applications from institutions to establish or enhance core facilities (laboratory, clinical, population-based, or computer-based) that will directly support cancer research programs to advance knowledge of the causes, prevention, and/or treatment of cancer or improve quality of life for patients with and survivors of cancer.
  Award: Up to $3M (total costs) for the first 2 years and up to $1M (total costs) for each subsequent year; Maximum duration: 5 years.

- *High Impact/High Risk Research Awards (HIHR) (RFA R-19.2 HIHR)*
  Provides short-term funding to explore the feasibility of high-risk projects that, if successful, would contribute major new insights into the etiology, diagnosis, treatment, or prevention of cancers.
  Award: Up to $200,000 (total costs); Maximum duration: 2 years.

- *Early Translational Research Awards (ETRA) (RFA-R-19.2 ETRA)*
  Supports projects that "bridge the gap" between promising new discoveries achieved in the research laboratory and commercial development for a therapeutic, device, or diagnostic assay through activities including preclinical proof-of-principle data that demonstrate applicability to the planned clinical scenario and preclinical toxicology and formulation to de-risk the development of lead compounds or devices. Any not-for-profit institution that conducts research is eligible to apply for funding under this award mechanism. Presentation of a time line with stage gates for development is required. A public or private company is not eligible.
  Award: up to $2M in total costs over a period of 1-2 years.

- *Collaborative Action Program to reduce liver cancer mortality in Texas: Collaborative Action Center Award (RFA-R-19.2 CAP: CAC)*

Supports a Collaborative Action Center whose function will be to: (1) promote interactions and collaborations across the CAP Research Awards funded under the companion RFA, R-19.2 CAP:RA; (2) provide opportunities for academic content experts, health care providers and community stakeholders to exchange ideas and to explore new opportunities to impact the rise of hepatocellular cancer (HCC) in Texas and (3) educate health care providers and the public on best practices to alter the trajectory of HCC in Texas.
Award: CPRIT plans to make one award. Up to $3M in total costs over a period of 5 years.

- *Collaborative Action Program to reduce liver cancer mortality in Texas: Investigator Initiated Research Awards (RFA-R-19.2 CAP: RA)*
  Supports investigator-initiated research projects designed to understand the reasons for the increased incidence of HCC in Texas, to identify risk factors for cirrhosis and HCC, to identify biomarkers for HCC early detection, and to develop and implement prevention and early detection strategies.
  Award: CPRIT plans to make multiple awards in response to this RFA. Up to $500,000 each in total costs per year for 5 years.

Product Development Research Program Update

Product Development Research FY 2018 Cycle 2

The Oversight Committee approved three product development awards at its August meeting. Magnolia Neurosciences acquired one of the newly-awarded CPRIT companies, Korysso Therapeutics, in August and renamed it Magnolia Tejas. The Oversight Committee's approval of the Korysso award was contingent upon the company satisfying several conditions identified by the Product Development Review Council (PDRC) during the due diligence review. Korysso/Magnolia Tejas worked with CPRIT to address the remaining contingencies, which it completed this month. CPRIT and the company will execute the award contract in early 2019.

CPRIT's PDRC requested more information to complete their review for two other applications in the 18.2 review cycle. The PDRC met on October 17 to review additional information provided by one applicant and declined to recommend the application for funding. The one company remaining from the 18.2 review cycle plans submitted requested information to CPRIT this month for PDRC review in January. If the PDRC recommends the application for funding, CPRIT will present that recommendation to the PIC and the Oversight Committee in February.

Product Development Research Applications FY 2019 Cycle 1

The Oversight Committee released the RFAs for the Product Development FY 2019 Award Cycle 1 in mid-May and accepted applications through August 8. Applicants submitted 38 proposals.

Table 3: FY 2019.1 (19.1) Application Data by Mechanism

Mechanism	Apps	Funds Requested	In Person	Funds Requested	Due Diligence	Funds Requested
Texas Company	5	$42,389,966	2	$16,680,008	2	$16,680,008
Relocation Company	8	$113,790,609	4	$63,474,499	3	$49,363,074
Seed Company	25	$64,956,585	11	$29,569,259	4	$11,912,313
TOTAL	**38**	**$221,137,160**	**17**	**$109,723,766**	**9**	**$77,955,395**

FY 2019 Cycle 2 Product Development Research RFAs

CPRIT released three RFAs on December 5 and will accept applications through January 30, 2019. Following peer review and due diligence, the Chief Product Development Officer will present the PDRC's recommendations to the PIC and Oversight Committee at the August 2019 Oversight Committee meeting. We anticipate that CPRIT will continue to receive a high number of Seed Award applications, including several resubmitted applications from review cycle 19.1.

The three 19.2 RFAs are:

- *Texas Company Product Development Research Award*
  Supports early-stage "start-up" and established companies in the development of innovative products, services, and infrastructure with significant potential impact on patient care. The proposed project must further the development of new products for the diagnosis, treatment, or prevention of cancer; must establish infrastructure that is critical to the development of a robust industry; or must fill a treatment or research gap. Companies must headquarter in Texas.
  Award: Maximum amount $20M over 36 months

- *Relocation Company Research Award*
  Supports early-stage "start-up" and established companies in the development of innovative products, services, and infrastructure with significant potential impact on patient care. The proposed project must further the development of new products for the diagnosis, treatment, or prevention of cancer; must establish infrastructure that is critical to the development of a robust industry; or must fill a treatment or research gap. Companies must relocate to Texas upon receipt of award.
  Award: Maximum amount $20M over 36 months

- *Seed Award for Product Development Research*
  Supports projects that are earlier in their development timeline than CPRIT's two other Product Development Awards, the Texas Company Award, and the Company Relocation Award. The proposed project must further the development of new products for the diagnosis, treatment, or prevention of cancer; must establish infrastructure that is critical to the development of a robust industry; or must fill a treatment or research gap. Company

applicants must headquarter in Texas or be willing to relocate to Texas upon receipt of award.
Award: Maximum amount of $3M over 36 months.

Prevention Program Update

FY 2019 Cycle 1 (19.1) Prevention Applications

CPRIT released four RFAs in June 2018 for the first review cycle of FY 2019. Twenty applications underwent peer review in Dallas on December 11-12. The Prevention Review Council (PRC) will consider these applications at their meeting on January 9, 2019, and review the two Dissemination of CPRIT-Funded Cancer Control Interventions applications that CPRIT received by December 5. Dr. Garcia will present the PRC's recommendations to the PIC and the Oversight Committee in February.

Table 4: FY 2019.1 (19.1) Application Data by Mechanism

Mechanism	Received	Funds Requested
Evidence-based Cancer Prevention Services	9	$12,304,996
Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations	7	$15,830,685
Tobacco Control and Lung Cancer Screening	4	$5,577,137
Dissemination of CPRIT-Funded Cancer Control Interventions	0	$0
TOTAL	**20**	**$33,712,818**

FY 2019 Cycle 2 Prevention RFAs

CPRIT released FY 2019 Cycle 2 RFAs (described below) on November 19. Applications are due February 20, 2019. CPRIT has scheduled peer review May 20 – 23, 2019. Dr. Garcia will present the Prevention Review Council's recommendations to the PIC and the Oversight Committee in August 2019.

FY 2019 Cycle 2 Prevention RFAs

- *Evidence-Based Cancer Prevention Services*
  Seeks projects that will deliver evidence-based cancer prevention and control clinical services. CPRIT will give priority to projects that propose to address CPRIT areas of emphasis and serve areas of the state not well addressed by current CPRIT funded projects.
  Award: Maximum of $1M over 36 months.

- *Tobacco Control and Lung Cancer Screening*
  Seeks programs on tobacco prevention and cessation, as well as screening for early detection of lung cancer. Through release of this RFA, CPRIT's goal is to stimulate more programs across the state, thereby providing greater access for underserved populations and reducing the incidence and mortality rates of tobacco-related cancers. This RFA seeks to promote and deliver evidence-based programming designed to significantly increase tobacco cessation among adults and/or prevent tobacco use by youth.
  Award: Maximum of $1M over 36 months.

- *Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations*
  Seeks to support coordination and expansion of evidence-based services to prevent cancer in underserved populations who do not have adequate access to cancer prevention interventions and health care, bringing together networks of public health and community partners to carry out programs tailored for their communities. Projects should identify cancers that cause the most burden in the community and use evidence-based models shown to work in similar communities to prevent and control these cancers. Currently funded CPRIT projects should propose to expand their programs to include additional types of prevention clinical services and/or an expansion of current clinical services into additional counties. In either case, the expansion must include delivery of services to nonmetropolitan and medically underserved counties in the state.
  Award: Maximum of $2M over 36 months.

- *Dissemination of CPRIT-Funded Cancer Control Interventions*
  Seeks to fund projects that will facilitate the dissemination and implementation of successful CPRIT-funded, evidence-based cancer prevention and control interventions across Texas. The proposed project should be able to develop one or more "products" based on the results of the CPRIT-funded intervention. The proposed project should also identify and assist others to prepare to implement the intervention and/or prepare for grant funding.
  Award: Maximum of $300,000 over 24 months.

Advisory Committees

- The Advisory Committee on Childhood Cancers will meet on January 8, 2019

- The Clinical Trials Advisory Committee will meet in Austin on January 21, 2019

Communications Update

Special Events

- Communications and Operations staff gathered feedback on reasons that CPRIT received no responses to the venue request for proposals (RFP), released in October for the *2020 CPRIT Innovations VI Conference*. Based on this information, we will revise and release a new RFP in early 2019.

Other activities

- Work on *CPRIT's 2018 Annual Report* continues and is due to the legislature by January 31, 2019.

- Communications and IT staff are finalizing the new CPRIT website. We anticipate a public launch in early January.

Social media

Facebook (last 28 days):
- Reach: 1,677
- Engagement: 291
- Most popular post: "CPRIT Scholar and @MDAnderson scientist Jim Allison was officially presented his Nobel Prize during a ceremony Monday. Sweden's King Carl XVI Gustaf presented the prize to Allison, the first MD Anderson Cancer Center scientist ever to receive the now 118-year-old honor."

Twitter (last 28 days):
- 16,400 impressions
- Top tweet: "CPRIT Scholar and @MDAndersonNews scientist Jim Allison was officially presented his Nobel Prize Monday in Sweden: https://cprit.us/2QQhIIE"

Twitter (November):
- 18,200 impressions
- Top tweet: "Congratulations to multiple CPRIT awardee and @UTSWNews professor Dr. Ralph DeBerardinis on being selected to receive the @TAMESTX 2019 Edith and Peter O'Donnell Award: https://cprit.us/2ThyizC."

Operations, Audit and Finance Update

- The McConnell & Jones audit team presented their audit report on CPRIT's FY 2018 financial statements to the Audit Subcommittee on December 6. McConnell & Jones reported that CPRIT presents the agency's financial statements "fairly" and found no deficiencies in any of CPRIT's internal controls or in compliance that they tested. CPRIT submitted the audit report to the Comptroller of Public Accounts as required by the Comptroller's rules.

- The Weaver audit team completed the internal audit report on the follow-up procedures for the State Auditor's Office (SAO) audit over CPRIT performance measures. Weaver concluded that CPRIT has closed all outstanding findings. Ms. McConnell distributed the report to the Audit Subcommittee. The Oversight Committee will consider the audit report for approval in February.

- CPRIT staff used the information in the internal audit report on the follow-up procedures to provide a written status report on December 14 to the SAO about CPRIT's progress on addressing the findings in the SAO audit.

- The Weaver team started field work on the Budget and Planning audit in December.

- With the assistance of numerous staff, I prepared draft packages of materials for upcoming legislative committee hearings on CPRIT's fiscal years 2020- 2021 request for appropriations and constitutional amendment(s) to authorize additional general obligation bonds to continue CPRIT after the current $3 billion authorization is exhausted.

Upcoming Subcommittee Meetings

Listed below are the regularly scheduled subcommittees in advance of the February 21, 2019, Oversight Committee meeting.

Because of the 2019 legislative session, CPRIT will hold **the February Oversight Committee meeting at the Texas Higher Education Coordinating Board, 1200 East Anderson Lane.**

Board Governance	February 7 at 10:00 a.m.
Audit	February 11 at 10:00 a.m.
Prevention	February 12 at 10:00 a.m.
Academic Research	February 13 at 10:00 a.m.
Product Development	February 14 at 10:00 a.m.
Nominations	February 15 at 10:30 a.m.

CPRIT will send an agenda, call-in information, and supporting material to the subcommittees one week prior to the meeting date.

******

CPRIT has awarded **1,321** grants totaling **$2.169 billion**

- 209 prevention awards totaling $223.1 million
- 1,112 academic research and product development research awards totaling $1.945 billion

Of the $1.945 billion in academic research and product development research awards,

- 30.5% of the funding ($592.8 million) supports clinical research projects
- 25.3% of the funding ($491.7 million) supports translational research projects
- 26.8% of funding ($522.0 million) supports recruitment awards
- 14.3% of the funding ($279.1 million) supports discovery stage research projects
- 3.1% of funding ($59.9 million) supports training programs.

CPRIT has 15 open Requests for Applications (RFAs)

- 3 Research Recruitment
- 5 Academic Research
- 3 Product Development Research
- 4 Prevention

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	WAYNE R. ROBERTS, CHIEF EXECUTIVE OFFICER
SUBJECT:	CPRIT ACTIVITIES UPDATE JANUARY 2019
DATE:	FEBRUARY 1, 2019

Topics in this memo cover the month of January 2019 and include preparation for the upcoming February 21 meeting, recent milestones in our fight against cancer, a staffing summary, CPRIT outreach efforts, CPRIT's 2018 Annual Report, legislative session activities, and updates from Compliance, Programs, and Operations.

Upcoming Oversight Committee Meeting

The Oversight Committee will meet February 21 at 10:00 a.m. in the board room at the Texas Higher Education Coordinating Board, 1200 E. Anderson Lane. Due to the legislative session, we are unable to hold our meeting at the Capitol. CPRIT will post the final agenda for the Oversight Committee meeting by February 13; I have attached a tentative agenda. We have seven members of the Oversight Committee and do not expect new appointments before the February meeting. One member has already notified me that he will be unable to attend the meeting. A quorum of five members is necessary to conduct official business. **Please notify me as soon as possible if you are unable to attend the February meeting or have travel arrangements that will cause you to arrive late or leave the meeting early.**

You will receive an email from CPRIT by February 11 with a link and password to access the Program Integration Committee's award recommendations via the grant award portal. The portal has supporting documentation regarding each project proposed for an award, including the application, CEO affidavit, summary statement, and grant pedigree. A summary of each award slate will also be available through the portal. All three programs will be proposing grant awards. Please allow some time to complete the individual conflict of interest checks and review the supporting material.

Oversight Committee members will receive an electronic copy of the agenda packet by February 14. Hard copies of the agenda packet will be available at the meeting.

PO Box 12097 | Austin, Texas 78711 | PH: 512-463-3190 | F: 512-475-2563 | cprit.texas.gov

Recent Milestones in the Fight Against Cancer

CPRIT Grantees in the News

- John Mendelsohn, M.D., president emeritus of The University of Texas MD Anderson Cancer Center, died January 7. The cause of death was glioblastoma. Dr. Mendelsohn was the third president of MD Anderson, serving in that capacity from 1996 to 2011. During that time *U.S. News & World Report* named MD Anderson the top cancer hospital and the institution consistently received more research grants from the National Cancer Institute and conducted more therapeutic clinical trials to evaluate new treatments than any other comparable entity.

  Dr. Mendelsohn was a pioneering research scientist in demonstrating how growth factors regulate the proliferation of cancer cells through a process that activates receptors on the cell surfaces. In the early 1980s, he began researching ways to fight cancer by blocking epidermal growth factor receptors with Gordon Sato and other colleagues at the University of California, San Diego. Their research led to development of the drug cetuximab (Erbitux™), which the FDA approved in 2004 for treating advanced colorectal cancer and in 2006 for head and neck cancer. In recognition of his outstanding academic achievements, Dr. Mendelsohn was elected to several of the nation's most prestigious organizations, including the Health and Medicine Division of the National Academies of Sciences and the Academy of Arts and Sciences.

- CPRIT Established Investigator Dr. David Johnson announced his plan to step down as Chair of the Department of Internal Medicine at UT Southwestern (UTSW). UTSW recruited Dr. Johnson, a national and international leader in the field of lung cancer biology and clinical care, in 2010 from Vanderbilt University Medical School. In addition to his leadership role at UTSW, he is a Past Chair of the American Board of Internal Medicine Board of Directors, a Past President of the American Society of Clinical Oncology (ASCO), and recipient of the 2016 ASCO Distinguished Achievement Award. Dr. Johnson served CPRIT as an early member of CPRIT's Scientific Review Council prior to joining UTSW.

- Texas Tech University recently named CPRIT grantee Min Kang, Ph.D., professor, Department of Pediatrics at Texas Tech University Health Science Center one of two recipients of the Chancellor's Council Distinguished Research Award. CPRIT has funded Dr. Kang's research with three individual investigator research awards focused on treatment of the childhood cancer neuroblastoma.

- Four El Paso news stations as well as the *El Paso Times* featured Dr. Jennifer Salinas's CPRIT project, "Pasos Para Prevenir Cancer: Obesity-related Cancer Prevention in El Paso." Dr. Salinas, an assistant professor at Texas Tech University Health Sciences Center, studies obesity and obesity-related illness and has focused her research and prevention work on the U.S.-Mexico border. This project addresses the challenge of rising obesity rates and obesity-related cancers in the El Paso community and provides education and outreach, healthcare

professional training, resource sharing and website development to assure long-term sustainability.

- The winter edition of *Cancer Today* features Bob Riter, a Prevention Program advocate reviewer. The article, "The Education of a Patient Advocate," is a companion to the feature describing his career path and experiences as a male breast cancer survivor. Advocate reviewers participate in and are a valuable part of CPRIT's peer review process.

Notable CPRIT Supported Accomplishments

- CPRIT Scholar David Taylor, Ph.D., assistant professor of molecular biosciences at The University of Texas at Austin, has invented a way to build synthetic structures from proteins. The new method, published in the journal *Nature Chemistry*, and dubbed "SUpercharged PRotein Assembly (SuPrA)," mimics the way that proteins in living organisms work as they make the molecular machines that carry out the different functions of life.

- CPRIT Scholar Kyle Miller, Ph.D., associate professor of molecular biosciences at The University of Texas at Austin and Susan Rosenberg, Ph.D., professor of molecular and human genetics at Baylor College of Medicine, have used an unconventional approach involving bacteria to discover human proteins that can lead to DNA damage and promote cancer. The research, supported in part by a CPRIT Individual Investigator Research Award and published in the journal *Cell*, found proteins known to be involved in cancer as well as many others not suspected of being cancer-causing. This finding is important as it may lead to new ways to identify people who are likely to develop cancer, giving their oncologists strategies to prevent it, slow it down, or catch it early.

- CPRIT Scholar Matthew Ellis, M.B., B.Chir., Ph.D., professor of medicine at Baylor College of Medicine, is using both genomics and proteomics to identify new molecules that could lead to novel treatments for breast cancer. The latest research from his group, published in the *Proceedings of the National Academy of Sciences*, pointed to a new target, *DPYSL3,* a gene that affects cell proliferation and the ability of breast cancer cells to move and metastasize. CPRIT-supported infrastructure has enabled Baylor College of Medicine and Dr. Ellis to become a national leader in using proteogenomic strategies to develop new precision medicine approaches to cancer care.

- At its 2018 annual meeting, the American Society of the Radiation Oncologists (ASTRO) recognized the Light and Salt Association's cancer support network with a $10,000 award. ASTRO is the premier radiation oncology society in the world. Light and Salt's cancer support network is a CPRIT-funded project focusing on Asian American communities. These communities have large foreign-born populations that, in addition to high cancer burdens, have structural barriers to quality health care access. The CPRIT project establishes culturally and linguistically competent cancer prevention and screening programs targeting colon, breast, cervical and liver cancer, and healthy eating and survivor support to effectively reduce service gaps and disparities.

- OncoNano Medicine, Inc. announced that the FDA has accepted its Investigational New Drug (IND) application for ONM-100, an intravenously administered imaging agent to detect tumors and metastatic lymph nodes in solid cancers during surgery. OncoNano also received Fast Track designation from the FDA for ONM-100. Yalia Jayalakshmi, Vice President, Clinical Development at OncoNano Medicine reports, "With these responses and the emerging clinical data demonstrating the potential of the product in multiple types of solid tumors, including breast, head and neck, esophageal and colorectal cancers, we are well positioned to advance ONM-100 into a Phase 2 clinical study in 2019." The Oversight Committee approved a $6 million CPRIT Product Development Research Program award to OncoNano in 2014.

- Bellicum Pharmaceuticals, Inc. reports its first data on BPX-601, a novel CAR-T drug with a built-in application switch to boost its effects, and says initial results show signs of biologic activity. Data from 12 patients enrolled in a Phase 1/2 dose escalation study in PSCA-positive metastatic pancreatic cancer treated with the CAR-T drug showed that four out of six evaluable patients had stabilized disease, with two patients' tumors shrinking at least 20%. More importantly, the results suggest BPX-601 is working as intended. Emboldened by the early readout, Bellicum reports that it is now adding additional tumor types to the trial and moving ahead with plans for repeat rimiducid dosing to extend the activation phase of treatment. The safety profile of BPX-601 also looks clean so far, with no cases of cytokine-release syndrome (CRS) and neurotoxicity that have been an issue with some other CAR-Ts treatments. Bellicum is the recipient of two CPRIT Product Development Research Program awards, including a $5.7 million award in 2011 and a $16.9 million award in 2016.

- Salarius Pharmaceuticals announced a merger agreement with Flex Pharma to accelerate clinical development of their novel epigenetic therapy for Ewing sarcoma, a pediatric bone cancer with limited treatment options. Salarius recently completed a $6.4 million private placement, that will fund the combined company to mid-2020, allowing it to report early cohort data from an ongoing Phase 1 Ewing sarcoma trial. Salarius' lead compound, Seclidemstat, targets the epigenetic dysregulation underlying Ewing sarcoma, a devastating pediatric, adolescent, and young adult bone cancer for which no targeted therapies currently exist. The company is currently enrolling patients in an open-label Phase 1 dose escalation/expansion study, which the company expects to conclude in 2020. Salarius is also preparing to initiate additional studies in advanced solid tumors, including prostate, breast, and ovarian cancers. The Oversight Committee approved an $18.7 million Product Development Research Program award to Salarius in 2016.

- The US Patent Office granted the 100th patent to Immatics, underscoring the company's lead role in the field of innovative immunotherapies. According to the company, this is a significant achievement and demonstrates the breadth of Immatics' innovation power and quality of its science. Immatics' strong patent portfolio enables the company to develop its pipeline of cancer immunotherapies, to protect Immatics' innovations, and to safeguard the company's technology investments. Immatics US Inc. received a $19.7 million CPRIT Product Development Research Program award in 2015.

Personnel

CPRIT has filled 34 of its 35 authorized full-time equivalent (FTE) positions. Dr. Cindy WalkerPeach will start work as CPRIT's Chief Product Development Officer on February 11.

CPRIT Outreach

- Chief Prevention Officer Becky Garcia and Senior Program Manager for Prevention Ramona Magid attended MD Anderson's Executive Advisory Panel Meeting on January 18 to present an update on CPRIT and the 2018 Texas Cancer Plan.

- Chief Scientific Officer James Willson was an invited speaker at the annual Rice University Medical Speaker's Conference on January 19.

- Dr. Willson attended the UT Southwestern Kidney Cancer Program External Advisory Committee meeting in Dallas on January 24.

- Dr. Garcia and Ramona Magid met with Greg Hartman, Vice Chancellor for Strategic Initiatives, Texas A&M University System on January 25. He is new to his position and requested an overview of CPRIT's prevention opportunities and initiatives.

- On January 31 Senior Program Manager for Product Development Rosemary French attended a monthly learning series, "Health, Design and Business: Design Thinking for Health Innovation" at the Texas Health CoLab at the Dell Medical School in Austin.

- I will provide a keynote address, "The Success, Impact and Future of The Cancer Prevention and Research Institute of Texas" at the annual Texas Healthcare & Bioscience Institute (THBI) Summit on February 11. THBI will honor CPRIT Scholar and Nobel Laureate Jim Allison, Ph.D., and House Appropriations Chair Rep. John Zerwas, M.D. at its Luminary Dinner that evening. Deputy Executive Officer and General Counsel Kristen Doyle, Ms. French, and Dr. WalkerPeach plan to attend the summit.

CPRIT's 2018 Annual Report

I submitted CPRIT's *2018 Annual Report* to the Governor, Lt. Governor, the Speaker of the House of Representatives, and members of the Legislature on January 31. State law requires CPRIT to report annually on several statutory directives. We restructured the *2018 Annual Report* to emphasize the emerging issues facing the Legislature as CPRIT invests the final 25% of its constitutional bond authority. The *2018 Annual Report* also highlights major grantee accomplishments and metrics illustrating how CPRIT is meeting Texans' high expectations set at the Institute's creation. Each of CPRIT's programs provides examples of CPRIT's investments in human, intellectual, and capital infrastructure that are leading to innovation and new opportunities to fight cancer in Texas.

86th Legislative Session

Legislation Affecting CPRIT

As of January 31, legislators have filed three bills directly affecting CPRIT:

- *House Joint Resolution 12* (Zerwas) – Authorizes a second $3 billion in General Obligation Bonds for cancer research and prevention to be submitted to voters at the November 5, 2019, general election.

- *House Bill 39* (Zerwas) and *Senate Bill 438* (Nelson) – Removes the restriction against new grant awards in FY 2023 if general obligation bonds are authorized by voters or another funding source is used for FY 2023 and beyond.

- *Senate Bill 200* (Schwertner) – Requires CPRIT to develop a plan for self-sufficiency once the 2007 general obligation bond authorization expires.

In addition to these bills, the General Appropriations Bill (HB 1) also affects CPRIT's operations. HB 1 includes a $164 million appropriation from the Economic Stabilization Fund (aka the "Rainy Day" fund) to address CPRIT's exceptional item request for the fiscal biennium 2020-2021. The Senate's filed version does not include funding for the exceptional item request. The House and Senate budget conferees will address the request in a budget conference when the appropriations bill is closer to final passage. If the budget adopted by the House and Senate includes the $164 million appropriation, CPRIT will be able to award grants in fiscal years 2020 and 2021 at the same level ($280 million annually) as it has done for the past several years.

I anticipate that the Speaker of the House may refer HJR12 and HB39 to the House Committee on Public Health, chaired by Representative Senfronia Thompson, for public hearings. It is possible that these bills will be referred to the Appropriations Committee. The Lt. Governor may refer SB200 and SB438 to the Senate Committee on Health and Human Services, chaired by Senator Lois Kolkhorst. However, the bills may be referred to the Finance Committee.

Committee Hearings

Ms. McConnell and I presented CPRIT's budget requests to the Senate Committee on Finance, chaired by Senator Jane Nelson, on January 23. We anticipate testifying before the House Committee on Appropriations, chaired by Representative John Zerwas, sometime in the next few weeks. Several advocates testified to the committee in support of CPRIT. You can see their testimony on the archived committee video here (advocates' testimony begins at 3:03.)

Legislative Outreach

I briefed the following members and/or members' staff on CPRIT's operations and legislative issues set for consideration by the 86th Texas Legislature:

- Representative John Zerwas (January 9) Ms. Doyle and Chief Operating Officer Heidi McConnell joined me.
- Senator Kirk Watson's staff (January 10) Ms. Doyle and Ms. McConnell joined me.
- Lieutenant Governor Dan Patrick's staff (January 10) Ms. Doyle and Ms. McConnell joined me.
- Senator Flores' staff (January 24)
- Representative John Wray (January 30)
- Representative Cole Hefner's staff (January 30)
- Representative Rick Miller (January 31)
- Senator Dawn Buckingham (January 31)
- Representative Lynn Stucky (January 31)

Compliance Program Update

Submission Status of Required Grant Recipient Reports

CPRIT's grants management system (CGMS) produces a summary of delinquent reports each week; this is the primary source used by CPRIT's compliance staff to follow up with grantees. CPRIT typically has 560+ grants that are either active or wrapping up grant activities and receives an average of 560 grantee reports each month.

As of January 23, four entities had not filed 35 Academic Research reports and one Prevention report. CPRIT's Grant Accountants and Compliance Specialists review and process incoming reports and reach out to grantees to resolve filing issues. In most cases, CPRIT does not disburse grant funds until the grantee files the required reports. In some instances, grantee institutions may be ineligible to receive a future award if the grantee does not submit the required reports.

Financial Status Report Reviews

CPRIT's Compliance Specialists performed 198 second-level reviews of grantee Financial Status Reports (FSRs) during the months of December and January. Twenty-two FSRs (11%) required resubmission due to insufficient or inaccurate documentation submitted by the grantee. CPRIT's grant accounting staff completes the initial review of the FSRs and supporting documentation before routing them to the Compliance Specialists for final review and disposition.

Single Audit Tracking

Compliance Specialists track the submission of grantees' independent audit reports and the resolution of issues identified in these reports. Grantees who expend $750,000 or more in state awards in the grantee's fiscal year must submit a single independent audit, a program specific audit, or an agreed upon procedures engagement. The grantee submits the independent audit report with audit findings to CPRIT within 30 days of receipt, but no later than 9 months after the grantee's fiscal year end.

Compliance Specialists are working with one grantee to remediate audit findings. CPRIT gives grantees 30 days from receipt of the audit to submit supporting documentation to demonstrate remediation efforts. Currently, there is one grantee with a delinquent audit. Grantees are unable to receive reimbursements or advances if they are delinquent in filing the required audit and corrective action plan unless the grantee requested additional time by the due date of the required audit and CPRIT's CEO approved the request.

Desk Reviews

Compliance Specialists performed 17 desk-based financial monitoring reviews during the months of December and January. Desk reviews verify that grantees expend funds in compliance with specific grant requirements and guidelines and may also target an organization's internal controls, current and past fiscal audits, and timeliness of required grantee report submission. Compliance Specialists are working with five grantees to remediate desk review findings.

On-Site Reviews

Compliance Specialists conducted five on-site reviews during December and January. On-site reviews examine the grantee's financial and administrative operations, subcontract monitoring, procurement and contracting procedures, inventory procedures, personnel policies and procedures, payroll and timesheet policies, travel policies and records, and single audit compliance. Compliance Specialists are working with two grantees to remediate on-site review findings.

Annual Compliance Attestation

CPRIT requires grantees to submit an annual Attestation Form, demonstrating compliance with statutory and administrative grant requirements, CPRIT's policies and procedures, grant contract terms, and the Uniform Grant Management Standards (UGMS). This opportunity to self-report, in the form of a checklist, provides a baseline of grantee compliance and allows Compliance Specialists to proactively work with grantees towards full compliance prior to a desk review or on-site review. As of January 25, 2019, all Grantees have submitted the required Attestation to CPRIT.

Training and Support

CPRIT staff conducted a new grantee training webinar on January 10 for Texas Southern University. The training covered grant reporting requirements, administrative rule changes, grant closeout, and an overview of the compliance program including fraud, waste, and abuse reporting. Pursuant to Texas Administrative Code §703.22, new Grantees are required to complete an initial compliance training program prior to receiving disbursement of Grant Award funds.

Academic Research Program Update

FY 2019 Cycle 1 (19.1) RFAs Update

The Scientific Review Committee submitted their award recommendations for first the first award cycle of FY 2019. The Program Integration Committee will consider the recommendations on February 7. The Oversight Committee will vote to approve the awards at its February 21 meeting. CPRIT received 389 applications in response to five RFAs for individual investigator research awards. The proposals address CPRIT priorities including: untargeted awards, cancer in children and adolescents, clinical translations, computational biology and presentation and early detection.

Table 1: FY 2019.1 (19.1) Application Data by Mechanism

Mechanism	Rec'd	Funds Requested	In Full Review	Funds Requested	Recomm by SRC	SRC Funds Recomm
Individual Investigator Research Award (IIRA)	261	$233,976,917	144	$126,157,080	29	$26,021,344
IIRA for Cancer in Children and Adolescents	35	$44,382,130	24	$29,026,405	7	$7,889,942
IIRA for Clinical Translation	33	$52,321,758	23	$37,874,514	5	$9,576,748
IIRA for Computational Biology	25	$20,580,933	12	$9,544,680	3	$2,677,342
IIRA for Prevention and Early Detection	35	$34,294,805	26	$26,970,288	3	$3,890,151
TOTAL	**389**	**$385,556,543**	**229**	**$229,572,967**	**47**	**$50,055,527**

Recruitment Summary Data

CPRIT received eight recruitment applications during recruitment cycles 19.4 - 19.6. Dr. Willson will present the SRC's award recommendations to the PIC and the Oversight Committee in February.

Table 2: FY 2019 Recruitment RFA data by Mechanism for Cycles 19.4 – 19.6

Mechanism	Received	Funds Requested	Recomm by SRC	Funds Requested
Recruitment Established Investigators	0	0	0	0
Recruitment Rising Stars	1	$4,000,000	1	$4,000,000
Recruitment of First-Time Tenure Track Faculty Members	7	$14,000,000	5	$10,000,000
TOTAL	**8**	**$18,000,000**	**6**	**$14,000,000**

FY 2019 Cycle 2 Academic Research RFAs

CPRIT released the RFAs for the second award cycle of FY 2019 (described below) on August 17, 2018 and received applications through January 30. CPRIT will convene the peer review panels in May. Dr. Willson will present the SRC's recommendations to the PIC and Oversight Committee in August.

- *Core Facility Support Awards (CFSA) (RFA R-19.2 CFSA)*
  Solicits applications from institutions to establish or enhance core facilities (laboratory, clinical, population-based, or computer-based) that will directly support cancer research programs to advance knowledge of the causes, prevention, and/or treatment of cancer or improve quality of life for patients with and survivors of cancer.
  Award: Up to $3M (total costs) for the first 2 years and up to $1M (total costs) for each subsequent year; Maximum duration: 5 years.

- *High Impact/High Risk Research Awards (HIHR) (RFA R-19.2 HIHR)*
  Provides short-term funding to explore the feasibility of high-risk projects that, if successful, would contribute major new insights into the etiology, diagnosis, treatment, or prevention of cancers.
  Award: Up to $200,000 (total costs); Maximum duration: 2 years.

- *Early Translational Research Awards (ETRA) (RFA-R-19.2 ETRA)*
  Supports projects that "bridge the gap" between promising new discoveries achieved in the research laboratory and commercial development for a therapeutic, device, or diagnostic assay through activities including preclinical proof-of-principle data that demonstrate applicability to the planned clinical scenario and preclinical toxicology and formulation to de-risk the development of lead compounds or devices. Any not-for-profit institution that conducts research is eligible to apply for funding under this award mechanism. Presentation of a time line with stage gates for development is required. A public or private company is not eligible.
  Award: up to $2M in total costs over a period of 1-2 years.

- *Collaborative Action Program to reduce liver cancer mortality in Texas: Collaborative Action Center Award (RFA-R-19.2 CAP: CAC)*

Supports a Collaborative Action Center whose function will be to: (1) promote interactions and collaborations across the CAP Research Awards funded under the companion RFA, R-19.2 CAP:RA; (2) provide opportunities for academic content experts, health care providers and community stakeholders to exchange ideas and to explore new opportunities to impact the rise of hepatocellular cancer (HCC) in Texas and (3) educate health care providers and the public on best practices to alter the trajectory of HCC in Texas.
Award: CPRIT plans to make one award. Up to $3M in total costs over a period of 5 years.

- *Collaborative Action Program to reduce liver cancer mortality in Texas: Investigator Initiated Research Awards (RFA-R-19.2 CAP: RA)*
  Supports investigator-initiated research projects designed to understand the reasons for the increased incidence of HCC in Texas, to identify risk factors for cirrhosis and HCC, to identify biomarkers for HCC early detection, and to develop and implement prevention and early detection strategies.
  Award: CPRIT plans to make multiple awards in response to this RFA. Up to $500,000 each in total costs per year for 5 years.

Product Development Research Program Update

Product Development Research FY 2018 Cycle 2

CPRIT's Product Development Review Council (PDRC) elected not to make final award recommendations for two applications in the second award cycle of FY 2018 until the companies provided additional information for review. The PDRC met twice (October 17, 2018, and January 14) to evaluate the additional information provided by the applicants, ultimately declining to recommend either application for funding.

Product Development Research Applications FY 2019 Cycle 1

CPRIT received 38 applications for the Product Development FY 2019 Award Cycle 1 by the August 8, 2018, deadline. After peer review and in-person presentations by the applicants, the PDRC convened January 11, 14, and 22 to conduct the due diligence review meeting for nine applications from the 19.1 award cycle.

The PDRC recommends that CPRIT fund one relocation proposal, one Texas company proposal, and three Seed applications totaling $30.7 million. The PDRC elected to not make a final recommendation decision on two applications from the 19.1 cycle, pending review of additional information from the applicants. The interim Chief Product Development Officer will present the PDRC's recommendations to the PIC and the Oversight Committee in February. If the PDRC decides to recommend awards to either of the two companies still under review, the Oversight Committee may take up the recommendation at the May or August meeting.

Table 3: FY 2019.1 (19.1) Application Data by Mechanism

Mechanism	Apps	Funds Req'd	In Person	Funds Req'd	Due Dilig.	Funds Req'd	PDRC recomm	Funds Req'd
Texas Company	5	$42.4M	2	$16.7M	2	$16.7M	1	$8.7M
Relocation Company	8	$113.8M	4	$63.5M	3	$49.4M	1	$13.1M
Seed Company	25	$65.0M	11	$29.6M	4	$11.9M	3	$8.9M
TOTAL	**38**	**$221.2M**	**17**	**$109.8M**	**9**	**$78.0M**	**5**	**$30.7M**

FY 2019 Cycle 2 Product Development Research RFAs

CPRIT released three RFAs on December 5, 2018 and accepted applications through January 30. Following peer review and due diligence, the Chief Product Development Officer will present the PDRC's recommendations to the PIC and Oversight Committee at the August 2019 Oversight Committee meeting. We anticipate that CPRIT will continue to receive a high number of Seed Award applications, including several resubmitted applications from review cycle 19.1.

The three 19.2 RFAs are:

- *Texas Company Product Development Research Award*
  Supports early-stage "start-up" and established companies in the development of innovative products, services, and infrastructure with significant potential impact on patient care. The proposed project must further the development of new products for the diagnosis, treatment, or prevention of cancer; must establish infrastructure that is critical to the development of a robust industry; or must fill a treatment or research gap. Companies must headquarter in Texas.
  Award: Maximum amount $20M over 36 months

- *Relocation Company Research Award*
  Supports early-stage "start-up" and established companies in the development of innovative products, services, and infrastructure with significant potential impact on patient care. The proposed project must further the development of new products for the diagnosis, treatment, or prevention of cancer; must establish infrastructure that is critical to the development of a robust industry; or must fill a treatment or research gap. Companies must relocate to Texas upon receipt of award.
  Award: Maximum amount $20M over 36 months

- *Seed Award for Product Development Research*
  Supports projects that are earlier in their development timeline than CPRIT's two other Product Development Awards, the Texas Company Award, and the Company Relocation Award. The proposed project must further the development of new products for the diagnosis, treatment, or prevention of cancer; must establish infrastructure that is critical to the development of a robust industry; or must fill a treatment or research gap. Company

applicants must headquarter in Texas or be willing to relocate to Texas upon receipt of award.
Award: Maximum amount of $3M over 36 months.

Prevention Program Update

FY 2019 Cycle 1 (19.1) Prevention Applications

CPRIT released four RFAs in June 2018 for the first review cycle of FY 2019. Twenty applications underwent peer review in Dallas on December 11-12. The Prevention Review Council (PRC) met on January 9 to consider these applications and review the two "Dissemination of CPRIT-Funded Cancer Control Interventions" applications that CPRIT received by December 5. Dr. Garcia will present the PRC's recommendations to the PIC and the Oversight Committee in February.

Table 4: FY 2019.1 (19.1) Application Data by Mechanism

Mechanism	Received	Funds Requested
Evidence-based Cancer Prevention Services	9	$12,304,996
Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations	7	$15,830,685
Tobacco Control and Lung Cancer Screening	4	$5,577,137
Dissemination of CPRIT-Funded Cancer Control Interventions	2	$597,030
TOTAL	**20**	**$34,309,848**

FY 2019 Cycle 2 Prevention RFAs

CPRIT released FY 2019 Cycle 2 RFAs (described below) on November 19, 2018. Applications are due February 20. CPRIT has scheduled peer review May 20 – 23. Dr. Garcia will present the PRC's recommendations to the PIC and the Oversight Committee in August.

FY 2019 Cycle 2 Prevention RFAs

- *Evidence-Based Cancer Prevention Services*
  Seeks projects that will deliver evidence-based cancer prevention and control clinical services. CPRIT will give priority to projects that propose to address CPRIT areas of emphasis and serve areas of the state not well addressed by current CPRIT funded projects.
  Award: Maximum of $1M over 36 months.

- *Tobacco Control and Lung Cancer Screening*
  Seeks programs on tobacco prevention and cessation, as well as screening for early detection of lung cancer. Through release of this RFA, CPRIT's goal is to stimulate more programs

across the state, thereby providing greater access for underserved populations and reducing the incidence and mortality rates of tobacco-related cancers. This RFA seeks to promote and deliver evidence-based programming designed to significantly increase tobacco cessation among adults and/or prevent tobacco use by youth.
Award: Maximum of $1M over 36 months.

- *Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations*
  Seeks to support coordination and expansion of evidence-based services to prevent cancer in underserved populations who do not have adequate access to cancer prevention interventions and health care, bringing together networks of public health and community partners to carry out programs tailored for their communities. Projects should identify cancers that cause the most burden in the community and use evidence-based models shown to work in similar communities to prevent and control these cancers. Currently funded CPRIT projects should propose to expand their programs to include additional types of prevention clinical services and/or an expansion of current clinical services into additional counties. In either case, the expansion must include delivery of services to nonmetropolitan and medically underserved counties in the state.
  Award: Maximum of $2M over 36 months.

- *Dissemination of CPRIT-Funded Cancer Control Interventions*
  Seeks to fund projects that will facilitate the dissemination and implementation of successful CPRIT-funded, evidence-based cancer prevention and control interventions across Texas. The proposed project should be able to develop one or more "products" based on the results of the CPRIT-funded intervention. The proposed project should also identify and assist others to prepare to implement the intervention and/or prepare for grant funding.
  Award: Maximum of $300,000 over 24 months.

Advisory Committees

- The Advisory Committee on Childhood Cancers met on January 8.
- The Clinical Trials Advisory Committee met in Austin on January 21.
- The University Advisory Committee will meet in Houston on February 25.

Communications Update

Special Events

- CPRIT released a revised request for proposals seeking hotel and conference venues for the *2020 CPRIT Innovations VI Conference*. Responses are due on February 8.

Other activities

- CPRIT launched its new website January 13. CPRIT officially announced the new website via our listserv and social media channels on January 31. With the launch of the new website, Communications will release more content through the CPRIT News Room section. Plans include new video releases, profiles of CPRIT grantees, and posting of events such as legislative committee hearings. Social media will be used to link people to the website.

- Communications has created a new 2018 CPRIT highlights video. It also revised existing informational materials including the "CPRIT Reauthorization," "Real Momentum-Measurable Results" and "Texans Conquer Cancer" fact sheets. Communications will update all reports after the February Oversight Committee meeting. In addition, CPRIT plans to launch new videos in February and March.

Social media

Facebook (last 28 days):
- Reach: 1,003
- Engagement: 306
- Most popular post: CPRIT Scholar and @MDAnderson scientist Jim Allison was officially presented his Nobel Prize during a ceremony Monday. Sweden's King Carl XVI Gustaf presented the prize to Allison, the first MD Anderson Cancer Center scientist ever to receive the now 118-year-old honor.

Twitter (December):
- 9,700 impressions
- Top tweet: CPRIT Scholar and @MDAndersonNews scientist Jim Allison was officially presented his Nobel Prize Monday in Sweden: https://cprit.us/2QQhIIE.

Twitter (January):
- 16,800 impressions
- Top tweet: A team led by CPRIT-funded researchers at @UTAustin and @bcmhouston has applied an unconventional approach involving bacteria to discover human proteins that can lead to DNA damage and promote cancer: https://cprit.us/2VGgvTW.

Operations, Audit and Finance Update

The Weaver audit team completed the reports of the Budget and Planning and State Reporting internal audits. The Audit Subcommittee will review these reports, which CPRIT will present to the Oversight Committee for approval at the February 21 meeting.

Subcommittee Meetings

The Special Issues Subcommittee met on January 18 to discuss legislative issues.

Listed below are the regularly scheduled subcommittees in advance of the February 21 Oversight Committee meeting.

Because of the 2019 legislative session, CPRIT will hold **the February 21 Oversight Committee meeting at the Texas Higher Education Coordinating Board, 1200 East Anderson Lane.**

Board Governance	February 7 at 10:00 a.m.
Audit	February 11 at 10:00 a.m.
Prevention	February 12 at 10:00 a.m.
Academic Research	February 13 at 10:00 a.m.
Product Development	February 14 at 10:00 a.m.
Nominations	February 15 at 10:30 a.m.

CPRIT will send an agenda, call-in information, and supporting material to the subcommittees one week prior to the meeting date.

******

CPRIT has awarded **1,321** grants totaling **$2.169 billion**

- 209 prevention awards totaling $223.1 million
- 1,112 academic research and product development research awards totaling $1.945 billion

Of the $1.945 billion in academic research and product development research awards,

- 30.5% of the funding ($592.8 million) supports clinical research projects
- 25.3% of the funding ($491.7 million) supports translational research projects
- 26.8% of funding ($522.0 million) supports recruitment awards
- 14.3% of the funding ($279.1 million) supports discovery stage research projects
- 3.1% of funding ($59.9 million) supports training programs.

CPRIT has 7 open Requests for Applications (RFAs)

- 3 Research Recruitment
- 4 Prevention

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	VINCE BURGESS, CHIEF COMPLIANCE OFFICER
SUBJECT:	COMPLIANCE PROGRAM UPDATE
DATE:	FEBRUARY 11, 2019

The Chief Compliance Officer is responsible for apprising the Oversight Committee and the Chief Executive Officer of institutional compliance functions and activities, and assuring the Oversight Committee that controls are in place to prevent, detect and mitigate compliance risk. The required reporting includes quarterly updates to the Oversight Committee on CPRIT's compliance with applicable laws, rules and agency policies. In addition, the Compliance Officer is responsible for monitoring the timely submission status of required grant recipient reports and notifying the Oversight Committee and General Counsel of a grant recipient's failure to meaningfully comply with reporting deadlines.

Submission Status of Required Grant Recipient Reports

CPRIT's grants management system (CGMS) produces a summary of delinquent reports each week; this is the primary source used by CPRIT's compliance staff to follow up with grantees. CPRIT typically has 560+ grants that are either active or in close-out and receives an average of 560 grantee reports each month.

As of January 31, 2019, six entities had not filed 32 reports by the due date; 28 (88%) were Academic Research reports, three (9%) were Product Development Research reports, and one (3%) was a Prevention report. CPRIT's Grant Accountants and Compliance Specialists review and process incoming reports and reach out to grantees to resolve filing issues. In most cases, CPRIT does not disburse grant funds until the grantee files the required reports. In some instances, grantee institutions may be ineligible to receive a future award if the grantee does not submit the required reports.

Financial Status Report Reviews

CPRIT's Compliance Specialists performed 261 second-level reviews of grantee Financial Status Reports (FSRs) during the months of December and January. Thirty-eight FSRs (15%) required resubmission due to insufficient or inaccurate documentation submitted by the grantee. CPRIT's grant accounting staff completes the initial review of the FSRs and supporting documentation before routing them to the Compliance Specialists for final review and disposition.

Single Audit Tracking

Compliance Specialists track the submission of grantees' independent audit reports and the resolution of issues identified in these reports. Grantees who expend $750,000 or more in state awards in the grantee's fiscal year must submit a single independent audit, a program specific audit, or an agreed upon procedures engagement. The grantee submits the independent audit report with audit findings to CPRIT within 30 days of receipt, but no later than 9 months after the grantee's fiscal year end.

Compliance Specialists are working with one grantee to remediate audit findings. CPRIT gives grantees 30 days from receipt of the audit to submit supporting documentation to demonstrate remediation efforts. Currently, there is one grantee with a delinquent audit. Grantees are unable to receive reimbursements or advances if they are delinquent in filing the required audit and corrective action plan unless the grantee requested additional time by the due date of the required audit and CPRIT's CEO approved the request.

Desk Reviews

Compliance Specialists performed 19 desk-based financial monitoring reviews during the months of December and January. Desk reviews verify that grantees expend funds in compliance with specific grant requirements and guidelines and may also target an organization's internal controls, current and past fiscal audits, and timeliness of required grantee report submission. Compliance Specialists are working with five grantees to remediate desk review findings.

On-Site Reviews

Compliance Specialists conducted five on-site reviews during December and January. On-site reviews examine the grantee's financial and administrative operations, subcontract monitoring, procurement and contracting procedures, inventory procedures, personnel policies and procedures, payroll and timesheet policies, travel policies and records, and single audit compliance. Compliance Specialists are working with two grantees to remediate on-site review findings.

Annual Compliance Attestation

CPRIT requires grantees to submit an annual Attestation form, demonstrating compliance with statutory and administrative grant requirements, CPRIT's policies and procedures, grant contract terms, and the Uniform Grant Management Standards (UGMS). This opportunity to self-report, in the form of a checklist, provides a baseline of grantee compliance and allows Compliance Specialists to proactively work with grantees towards full compliance prior to a desk review or on-site review. As of January 31, 2019, all Grantees have submitted the required Attestation to CPRIT.

Training and Support

CPRIT staff conducted a new grantee training webinar on January 10 for Texas Southern University. The training covered grant reporting requirements, administrative rule changes, grant closeout, and an overview of the compliance program including fraud, waste, and abuse reporting. Pursuant to Texas Administrative Code §703.22, new Grantees are required to complete an initial compliance training program prior to receiving disbursement of Grant Award funds.

The first grantee compliance training series of CY 2019 has been scheduled for March 6-7. In each series, usually March, June, and October, there will be three trainings provided – one for Academic Research grantees, one for Product Development Research grantees, and one for Prevention grantees. Organizations with grants across multiple programs should attend the training that pertains to the majority of their awards.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	JAMES WILLSON, MD., CHIEF SCIENTIFIC OFFICER
SUBJECT:	ACADEMIC RESEARCH PROGRAM UPDATE
DATE:	FEBRUARY 21, 2019

FY 2019 Cycle 2 (19.2) Update

Table 1 displays an overview of FY 2019 Cycle 2 (19.2) data by mechanism. CPRIT has scheduled peer review for May 20- May 24, 2019 in Dallas. Dr. Willson will present the Scientific Review Committee's award recommendations to the Program Integration Committee and the Oversight Committee in August 2019.

Table 1: FY12019.2 Submissions and Funding Requested by Mechanism

FY2019.2 SUBMISSION AND FUNDS REQUESTED DATA		
Funding Mechanism	**# Applications Received**	**Funding Requested**
Core Facilities Support Awards	19	$96,666954
High Impact/High Risk Research Awards	97	$19,379,981
Early Translational Research Awards	28	$47,527,689
Collaborative Action Program to reduce liver cancer mortality in Texas: Collaborative Action Center Award	2	$5,999,901
Collaborative Action Program to reduce liver cancer mortality in Texas: Investigator Initiated Research Awards	15	$36,556,484
Total	**161**	**$206,131,009**

FY 2020 Cycle 1 (20.1) RFAs

CPRIT released FY2020 Cycle 1 RFAs (described below) on January 10, 2019. Applications are due on June 5, 2019. CPRIT has scheduled peer review October 17- 24, 2019 in Dallas. Dr. Willson will present the Scientific Review Council's recommendations to PIC and the Oversight Committee in February 2020.

PO Box 12097 | Austin, Texas 78711 | PH: 512-463-3190 | F: 512-475-2563 | cprit.texas.gov

- **Individual Investigator Research Awards (IIRA)**
  Supports applications for innovative research projects addressing critically important questions that will significantly advance knowledge of the causes, prevention, and/or treatment of cancer. Areas of interest include laboratory research, translational studies, and/or clinical investigations. Competitive renewal applications accepted.
  Award: Up to $300,000 per year. Exceptions permitted if extremely well justified; maximum duration: 3 years.

- **Individual Investigator Research Awards for Cancer in Children and Adolescents (IIRACCA)**
  Supports applications for innovative research projects addressing questions that will advance knowledge of the causes, prevention, progression, detection, or treatment of cancer in children and adolescents. Laboratory, clinical, or population-based studies are all acceptable. CPRIT expects the outcome of the research to reduce the incidence, morbidity, or mortality from cancer in children and/or adolescents in the near or long term. Competitive renewal applications accepted.
  Award: Up to $300,000 per year. Applicants that plan on conducting a clinical trial as part of the project may request up to $500,000 in total costs. Exceptions permitted if extremely well justified; maximum duration: 4 years.

- **Individual Investigator Research Awards for Prevention and Early Detection (IIRAP)**
  Supports applications for innovative research projects addressing questions that will advance knowledge of the causes, prevention, early-stage progression, and/or early detection of cancer. Research may be laboratory-, clinical-, or population- based, and may include behavioral/intervention, dissemination or health services/outcomes research to reduce cancer incidence or promote early detection. Competitive renewal applications accepted.
  Award: Up to of $300,000 per year for laboratory and clinical research; Up to $500,000 per year for population-based research. Exceptions permitted if extremely well justified; maximum duration: 3 years.

- **Individual Investigator Research Awards for Clinical Translation (IIRACT)**
  Supports applications which propose innovative clinical studies that are hypothesis driven and involve patients enrolled prospectively on a clinical trial or involve analyses of biospecimens from patients enrolled on a completed trial for which the outcomes are known. Areas of interest include clinical studies of new or repurposed drugs, hormonal therapies, immune therapies, surgery, radiation therapy, stem cell transplantation, combinations of interventions, or therapeutic devices.
  Award: Up to $400,000 per year. Maximum duration: 3 years. Applicants that plan on conducting a clinical trial as part of the project may request up to $600,000 in total costs and a maximum duration of 4 years. Exceptions permitted if extremely well justified.

Update on CPRIT's recruitment of outstanding cancer researchers to Texas.

To date CPRIT has supported the recruitment of 170 premier cancer researchers including: Established Investigators, with distinguished careers; Rising Stars, who have demonstrated extraordinary accomplishments during their initial years of independent research; and First Time Tenure Track Faculty, who have truly superior potential (Table 2). Scholars have been recruited to 18 Texas research institutions (Table 4) from institutions across the US and Europe (Chart 1).

Table 2: Scholars by SRC recommendations, acceptance and award funding by mechanism

Mechanism	Recommended by SRC	Accepted	% Acceptance	Award Funding	% Overall Scholar Funding	% Overall Research Funding*
Established Investigator	54	36	67%	$225,810,000	43%	14%
Rising Stars	26	16	62%	$57,970,000	11%	4%
First Time Tenure Track Faculty	157	114	73%	$232,320,000	45%	15%
Missing Link/ Clinical Investigator	6	3	50%	$5,880,000	1%	<1%
Total	**246**	**170**	**69%**	**$521,980,000**	**100%**	**33%**

*Academic Research Funding: $1,565,076,130

CPRIT Scholars include the 2018 Nobel Prize Winner in Physiology or Medicine, 9 members of the National Academies, 2 Members of the Howard Hughes Medical Institute, and 2 National Cancer Institute Outstanding Investigators. In addition to these and other accolades the Scholars have produced new peer reviewed research funding, patents, and publications (Table 3).

Table 3: Scholars by Mechanism, Award Funding, Return on Investment, and Retention*

Mechanism	Accepted	Award Funding	Follow-On Funds	Patents	Publications	Retention
REI	36	$225,810,000.00	$115,050,890.00	181	641	98%
RRS	16	$57,970,000.00	$36,644,284.00	0	295	98%
RFFT	114	$232,320,000.00	$130,430,528.00	35	783	97%
RML/RCT	4	$5,880,000.00	$13,624,589.00	1	49	100%
Total	**170**	**$521,980,000.00**	**$295,750,291.00**	**217**	**1768**	**98%**

*Data Sources: CGMS, PI Validation, NIH RePORTER, US National Library of Medicine, US Patent and Trademark Office

In addition to their individual accolades CPRIT Scholars are building new cancer research centers across Texas. For example, eleven CPRIT Scholars lead academic departments or centers and others have established new centers of research excellence including:

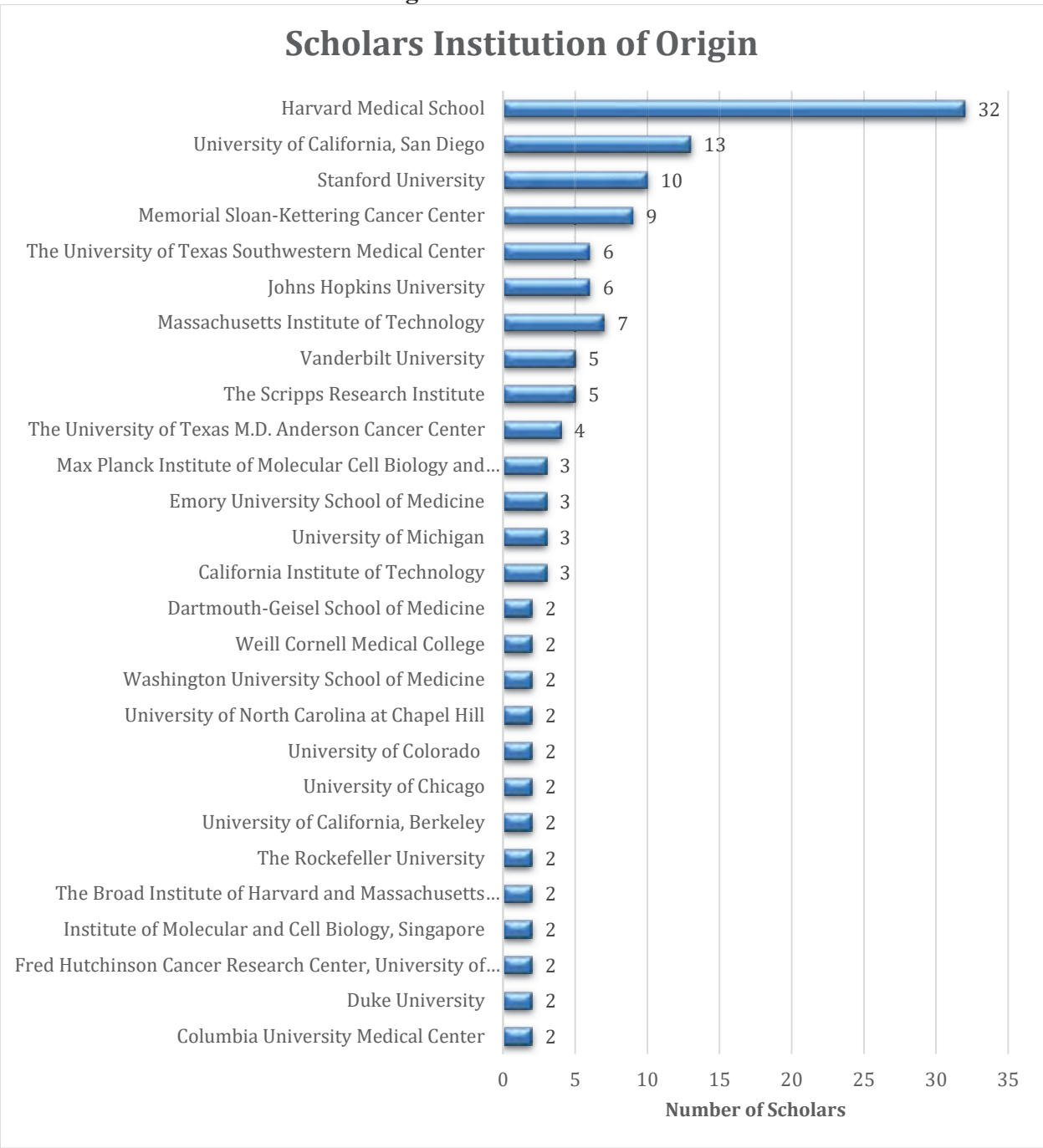
- The NIH Proteogenomic Translational Research Center and Data Analysis Center at Baylor College of Medicine led by CPRIT Scholars, Matthew Ellis, MB, B. Chir., Ph.D. and Bing Zhang, Ph.D. to understand breast cancer response and resistance to therapies;
- The National Science Foundation Center for Theoretical Physics at Rice awarded to CPRIT Scholars José Onuchic, Ph.D. and Herbert Levine, Ph.D., and linking Rice engineering and computational expertise with cancer biologists in the Texas Medical Center to study the evolution of cancer under a variety of different conditions;
- The Entertainment Industry Foundation's Stand Up to Cancer program established its "Immunology Dream Team" at MD Anderson under CPRIT Scholars James Allison, Ph.D. and Cassian Yee, M.D. to increase applicability of tumor immunotherapy. This same team leads the Parker Foundation Institute for Cancer Immunotherapy at MD Anderson;
- Baylor College of Medicine and Rice won a NIH Encyclopedia of DNA Elements Project (ENCODE) Center led by CPRIT Scholar Erez Lieberman Aiden, Ph.D. to identify the parts of the genome that control when genes turn on and off.

Table 4: Scholar Awards by Nominating Institution, # Awards and Funding

Institution	# Awards	Total Funding
The University of Texas Southwestern Medical Center	60	$159,725,527
The University of Texas M.D. Anderson Cancer Center	31	$105,000,000
Baylor College of Medicine	25	$70,500,000
The University of Texas at Austin	14	$40,000,000
Rice University	11	$39,104,127
The University of Texas Health Science Center at Houston	9	$22,506,000
The University of Texas Health Science Center at San Antonio	8	$23,892,505
The Methodist Hospital Research Institute	4	$22,986,494
University of Houston	3	$10,000,000
The University of Texas Medical Branch at Galveston	2	$7,881,402
Baylor University	1	$4,215,750
Texas A&M University	1	$2,000,000
Texas A&M University System Health Science Center	1	$1,800,000
Texas Tech University Health Sciences Center	1	$2,539,259
Texas Tech University Health Sciences Center at El Paso	1	$2,000,000
The University of Texas at Arlington	1	$823,067
The University of Texas Health Science Center at Tyler	1	$2,000,000
The University of Texas System	1	$5,000,000

*As of November 28, 2018
** Note 5 Scholars are pending acceptance

Chart 1: Scholars Institution of Origin



Note: 35 Institutions with 1 Scholar are not listed.

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	REBECCA GARCIA, PHD, CHIEF PREVENTION AND COMMUNICATIONS OFFICER
SUBJECT:	PREVENTION PROGRAM UPDATE
DATE:	FEBRUARY 11, 2019

FY 2019 Cycle 1 (19.1) Prevention Applications

CPRIT released four RFAs in June 2018 for the first review cycle of FY 2019. Twenty applications underwent peer review in Dallas on December 11-12. The Prevention Review Council (PRC) met on January 9, 2019, to review the results of the peer review panel plus the two Dissemination of CPRIT-Funded Cancer Control Interventions applications that CPRIT received by December 5. The Program Integration Committee (PIC) met February 7 and Dr. Garcia presents the PIC's recommendations to the Oversight Committee February 21.

FY 2019.1 (19.1) Application Data by Mechanism

Mechanism	Received	Funds Requested
Evidence-based Cancer Prevention Services	9	$12,304,996
Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations	7	$15,830,685
Tobacco Control and Lung Cancer Screening	4	$ 5,577,137
Dissemination of CPRIT-Funded Cancer Control Interventions	2	$ 597,030
TOTAL	**22**	**$34,309,848**

FY 2019 Cycle 2 Prevention RFAs

CPRIT released FY 2019 Cycle 2 RFAs (described below) on November 19. Applications are due February 20, 2019. CPRIT has scheduled peer review May 20 – 23, 2019. Dr. Garcia will present the Prevention Review Council's recommendations to the PIC and the Oversight Committee in August 2019.

FY 2020 Cycle 1 Prevention RFAs and schedule

The proposed schedule and RFAs to be released for FY 2020 Cycle 1 will be considered at the February 21 Oversight Committee meeting.

Timeline - Cycles 19.2 – 20.1

	19.2 **In progress**	**20.1** **For approval**
Submission	Feb. 20, 2019	Sept. 4, 2019
Peer Review	May 20-23, 2019	Dec. 9-12, 2019
PRC	July 8, 2019	Jan. 8, 2020
PIC	Aug. 6, 2019	Feb. 4, 2020
OC	Aug. 21, 2019	Feb. 19, 2020

Proposed RFAs

- *Evidence-Based Cancer Prevention Services*
  Seeks projects that will deliver evidence-based cancer prevention and control clinical services. CPRIT will give priority to projects that propose to address CPRIT areas of emphasis and serve areas of the state not well addressed by current CPRIT funded projects.
  Award: Maximum of $1M over 36 months.

- *Tobacco Control and Lung Cancer Screening*
  Seeks programs on tobacco prevention and cessation, as well as screening for early detection of lung cancer. Through release of this RFA, CPRIT's goal is to stimulate more programs across the state, thereby providing greater access for underserved populations and reducing the incidence and mortality rates of tobacco-related cancers. This RFA seeks to promote and deliver evidence-based programming designed to significantly increase tobacco cessation among adults and/or prevent tobacco use by youth.
  Award: Maximum of $1M over 36 months.

- *Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations*
  Seeks to support coordination and expansion of evidence-based services to prevent cancer in underserved populations who do not have adequate access to cancer prevention interventions

and health care, bringing together networks of public health and community partners to carry out programs tailored for their communities. Projects should identify cancers that cause the most burden in the community and use evidence-based models shown to work in similar communities to prevent and control these cancers. Currently funded CPRIT projects should propose to expand their programs to include additional types of prevention clinical services and/or an expansion of current clinical services into additional counties. In either case, the expansion must include delivery of services to nonmetropolitan and medically underserved counties in the state.
Award: Maximum of $2M over 36 months.

- *Dissemination of CPRIT-Funded Cancer Control Interventions*
  Seeks to fund projects that will facilitate the dissemination and implementation of successful CPRIT-funded, evidence-based cancer prevention and control interventions across Texas. The proposed project should be able to develop one or more "products" based on the results of the CPRIT-funded intervention. The proposed project should also identify and assist others to prepare to implement the intervention and/or prepare for grant funding.
  Award: Maximum of $300,000 over 24 months.

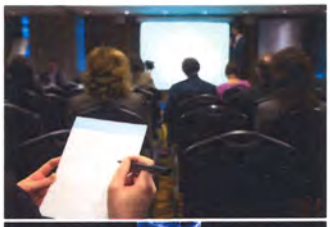
Other Activities

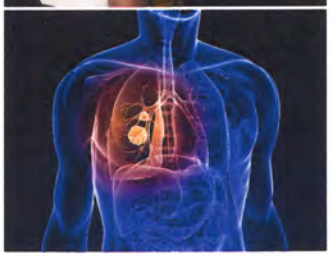
- Dr. Garcia and Ramona Magid attended MD Anderson's Executive Advisory Panel Meeting on January 18, 2019. They presented an update on CPRIT and the 2018 Texas Cancer Plan.

- Dr. Garcia and Ramona Magid met with Greg Hartman, Vice Chancellor for Strategic Initiatives, Texas A&M University System on January 25, 2019. He is new to his position and requested an overview of CPRIT's prevention opportunities and initiatives.

Providing Life Extending Results

5 Million Prevention Services





2.5 M Education & Training
for public and professionals

2.5 M Clinical services:
- ✓Breast, cervical, colorectal cancer screenings & diagnostics
- ✓Hepatitis B & C screening
- ✓HPV & Hepatitis B vaccinations
- ✓Tobacco cessation counseling and treatment
- ✓Genetic testing
- ✓Survivor programs and services

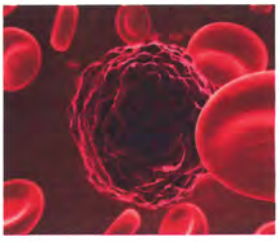
Providing Life Extending Results

Screening Outcomes as of August 2018

1,214,979
screenings/
diagnostics

355,689
people never
before screened

14,250
Precursors
detected



3,492
cancers detected

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	REBECCA GARCIA, PH.D. CHIEF PREVENTION AND COMMUNICATIONS OFFICER
SUBJECT:	COMMUNICATIONS UPDATE
DATE:	FEBRUARY 21, 2019

The following is an update of the agency's communication activities.

Earned Media (November 12, 2018 to February 7, 2019)

Coverage:

- 3 articles featured CPRIT
- 22 additional articles mentioned CPRIT (stories primarily focused on work of grantees)

Coverage Highlights: (see clipped articles following report)

- December 6, 2018, *Houston Business Journal, Houston cancer pharma co. begins Phase I trials after $6M Series B*
- December 8, 2018, *Houston Chronicle, Houston scientist Jim Allison presented Nobel*
- January 7, 2019, *Dallas Morning News, Texas cancer-fighting agency faces uncertain future as lawmakers prepare for new session*

Cancer Awareness Events

- CPRIT was active on social media for Cervical Health Awareness Month in January, sharing CPRIT produced videos featuring CPRIT grantees discussing their cervical cancer prevention efforts.

- For World Cancer Day (February 4) CPRIT released a video via social media featuring interviews with Dr. Jim Allison and a melanoma survivor who's benefited from his research.

- February is National Cancer Prevention Month and a video is being produced that will feature interviews of prominent CPRIT Prevention grantees. It will be posted on the Prevention Program's landing page and distributed via social media. Other prevention-related social media will also be posted during February.

Special Events

- Communications produced and released a 2018 CPRIT Highlights video in early January. It is posted on the homepage of CPRIT's new website. The video features Jim Allison's Nobel Prize, Livia Eberlin's Genius Award, Texas Tech University Health Sciences Center at El Paso's CPRIT Scholar recruit, Houston City Council's Proclamation for National Cancer Research Month, and the Liver Cancer CAP along with interviews of grantees, stakeholders and cancer survivors.

- CPRIT's new website was officially launched to the public on February 1 to coincide with the release of the 2018 Annual Report. New videos featuring CPRIT grantees James Brugarolas and Livia Eberlin were released, as well as the first in a series of grantee profiles for social media designed to drive visitors to the CPRIT Scholars section of the website. The new website design allows CPRIT to enhance its storytelling capabilities with a multi-channel platform for posting, curating and distributing CPRIT and related content.

- Wayne Roberts presented at the Texas Healthcare and Bioscience Institute (THBI) Summit on February 11 in Austin, Texas. His lecture was on *"The Success, Impact and Future of The Cancer Prevention and Research Institute of Texas."*

- CPRIT released a revised request for proposals seeking hotel and conference venues for the *2020 CPRIT Innovations VI Conference*. Responses were due on February 8.

Other activities

- Communications will interview Dr. Stephen Skapek of UT Southwestern after his presentation to the Oversight Committee on February 21. The interview will be used as part of a video on CPRIT-funded Childhood Cancer Projects.

- After the February Oversight Committee meeting, Communications will revise and update existing informational materials including the "CPRIT Reauthorization," "Real Momentum- Measurable Results" and "Texans Conquer Cancer" fact sheets and CPRIT's Momentum Report.

- A press release was sent out February 11 announcing the hire of Cindy WalkerPeach as Chief Product Development Officer.

Social Media Metrics

<u>Facebook (last 28 days)</u>**:**

- Reach: 3,334
- Engagement: 515
- Most popular post: Innovation in the State's Capital: Watch this video on the revolutionary MasSpec Pen, created by Dr. Livia Eberlin of the College of Natural

Sciences, UT Austin at The University of Texas at Austin. #CPRITImpact #MasSpecPen.

Twitter (January)**:**

- 18,300 impressions
- Top tweet: A team led by CPRIT-funded researchers at @UTAustin and @bcmhouston has applied an unconventional approach involving bacteria to discover human proteins that can lead to DNA damage and promote cancer: https://cprit.us/2VGgvTW.

Twitter (February)**:**

- 5,900 impressions
- Top tweet: Innovation in the State's Capital: Watch this video on the revolutionary #MasSpecPen, created by @Livia__se of @TexasScience at @UTAustin. #CPRITImpact.
- **Notable mention:** @SenJaneNelson In honor of World Cancer Day, I want to thank those who work hard each and every day - at @CPRITTexas and nationwide - to find a cure for this terrible disease. #txlege

Texas cancer-fighting agency faces uncertain future as lawmakers prepare for new session

Texas voters enlisted in a major offensive to fight cancer a dozen years ago, authorizing $3 billion in taxpayer-funded grants for research and prevention and vaulting the state to a leading national role in paying for such efforts.

With the money now running low, the call to re-enlist could come as early as this fall.

The state agency charged with distributing the grants -- the Cancer Prevention and Research Institute of Texas, commonly known as CPRIT -- estimates that it only has enough funding authority left to last the next couple of fiscal years, setting the stage for a debate over the fate of the anti-cancer effort during the Legislature's upcoming session, which begins Tuesday.

Already, proposals have been filed that sketch two divergent futures for CPRIT. One plan seeks a new referendum this November in which voters would be asked to approve an additional $3 billion in bonds for CPRIT to keep funding grants, while another would mandate that the agency devise a strategy for self-sufficiency with no new state money.

State Rep. John Zerwas, who has filed the resolution calling for the statewide vote, said continued taxpayer support for CPRIT is needed to sustain the momentum generated by the initial state investment.

"There are great (research) strides being made here" in Texas, said Zerwas, R-Richmond. "We have seen the fruits of our investment in cancer research already, and we have the opportunity to see that continue over the next decade" with additional state funding.

Voters created CPRIT in 2007 to oversee the issuance of $3 billion in taxpayer-backed bonds -- in increments of up to $300 million per year -- to pay "for research in Texas to find the causes of and cures for cancer." The vote, which came after an emotional campaign that featured high-profile cyclist and cancer survivor Lance Armstrong traveling across the state in a bus dubbed "Survivor One" to advocate for approval, has made Texas the second-largest source of public money for cancer research behind only the federal government.

Since then, supporters credit CPRIT with fostering multitudes of promising initiatives and helping shape a thriving life sciences industry in Texas, as well as increasing access to prevention and screening efforts throughout the state.

Immunologist James Allison, left, received his Nobel Prize from King Carl XVI Gustaf of Sweden during an award ceremony in December in Stockholm, Sweden. (JONATHAN NACKSTRAND/AFP/Getty Images)

CPRIT says the funding has lured 166 researchers and their labs to the state -- including James Allison at the University of Texas MD Anderson Cancer Center, who won the 2018 Nobel Prize for his work -- in addition to spurring 109 clinical trials and triggering $1.65 billion in follow-on investing by venture capital firms in startup companies seeded with agency grants.

"We had real hopes for CPRIT in 2007, but it has far exceeded what we expected," said James Gray, managing director for government relations at the American Cancer Society's legislative arm, the Cancer Action Network. "The infrastructure they have built (in terms of research labs and statewide prevention efforts) is going to have a long-term impact on this state, if we continue to invest in it."

Still, the price tag for the undertaking is causing some lawmakers to balk.

The annual debt service on previously issued bonds for CPRIT will cost the state $120.6 million in the current fiscal year, according to the agency. CPRIT's ability to authorize new bonds is dwindling, so it's seeking an additional $164 million from the state -- $82 million for each of the next two fiscal years -- to enable it to continue doling out grants at its current pace until it runs dry entirely, absent new grant-making authorization from voters. That $164 million would be in addition to the ongoing debt service for those years.

CPRIT has been giving out an average of $280 million in grants annually, but it estimates that the current fiscal year is the last in which it will be able to maintain that level. As things stand, it projects it will only be able to fund $198 million each in fiscal 2020 and fiscal 2021 before running out.

State Sen. Charles Schwertner, R-Georgetown, called the anti-cancer effort "unquestionably noble" but said he doesn't view it as an essential role of state government, particularly given numerous other demands on the state's budget. Schwertner has filed a bill requiring CPRIT to devise a path to self-sufficiency by utilizing licensing fees, patent royalties or other measures, a repeat of a similar bill he filed during the previous legislative session that garnered significant support from lawmakers but ultimately fell short.

"You're not going to find anyone opposed to the goal of curing cancer," Schwertner said in a written response to questions. "But with most of the (initial) $3 billion approved by Texas voters now spent, I think it is an appropriate time to ask what CPRIT's long-term future looks like when that money finally runs out."

But CPRIT Chief Executive Wayne Roberts said self-sufficiency wasn't the intent when voters established the agency in 2007. Had it been, Roberts said, CPRIT's grants would have gone mainly to relatively late-stage oncology companies on the verge of commercializing drugs and therapies, instead of to prevention and early-stage research and development.

CPRIT's grants contain royalty components for the state, but they've totaled only about $3.4 million so far. The figure might grow in coming years, although the amount is uncertain and could be far in the future.

"We fund early stage (research and companies) where there is not sufficient money for the proof of concept," Roberts said.

With the original $3 billion earmarked for grants now ebbing, however, the blueprint for CPRIT's future will be determined by state lawmakers -- and by voters, if a new referendum takes place this November.

Zerwas said he considers it reasonable to task the agency with identifying more opportunities to generate its own funding. But a mandate for self-sufficiency is too "dramatic of a change at this point in time," he said, and risks forfeiting much of what CPRIT has fostered in Texas, such as the prominent research labs it has attracted and the state's budding international reputation as a biomedical hub.

Meanwhile, funding for cancer research overall would take a big hit if CPRIT's money for grants withers away over the next few years, said Gray of the Cancer Action Network.

"In terms of (another entity) coming in with the same financial capacity, I don't see that happening," he said. "There are scarce resources for research funding right now. CPRIT is so critical in filling that gap."

Bob Sechler, Austin American-Statesman (TNS)

Houston cancer pharma co. begins Phase I trials after $6M Series B

By Chris Mathews

Houston Business Journal

After receiving $6 million in funding this summer, Houston-based Iterion Therapeutics Inc., formerly known as Beta Cat Pharmaceuticals, has begun Phase I clinical trials on its cancer drug.

Iterion closed on the $6 million Series B financing round led by Austin-based life science venture capital group Sante Ventures. The funding round also included investments from Houston-based angel investor group GOOSE (or Grand Order of Successful Entrepreneurs) Society of Texas and Houston-based heath care investor network AngelMD Inc. Iterion also received funds through a grant from the Cancer Prevention Research Institute of Texas, or CPRIT.

Iterion's lead cancer drug, dubbed Tegavivint, is an inhibitor of "nuclear beta-catenin activity and Wnt gene expression," which can both lead to developing various forms of cancer, according to a statement from the company. When proteins like beta-catenin get "turned on" in genetic signaling pathways, the process of cancer development can begin in certain people. Multiple non-clinical studies suggest that Tegavivint inhibits the activation of the cancer genes, while allowing the beta-catenin to resume its normal role in tissue function, according to the release.

Rahul Aras, president and CEO of Iterion Therapeutics, said that the $6 million in funding is being used for Phase I clinical trials in patients with desmoid tumors, which are commonly associated with beta-catenin mutations. Unlike other cancerous tumors, desmoid tumors are non-metastasizing and generally do not spread to other areas of the body, Aras said.

"The objective of the study is to start to define safety protocols for the product as well as the right therapeutic dose," Aras told the Houston Business Journal. "In addition to the safety that we will assess, we should be able to get some indication as to the preliminary activity of the drug and the potential efficacy against these tumors."

Aras said that Iterion has seen positive results from preclinical animal studies that Tegavivint could possibly be used to treat different kinds of blood cancers, soft tissue cancer and solid tumors.

Iterion Therapeutics rebranded itself from Beta Cat Pharmaceuticals in the last week or two, Aras said. The company works out of an office space in the Johnson & Johnson (NYSE: JNJ) JLABS at 2450 Holcombe Blvd. and employs eight people.

HOUSTON CHRONICLE

Houston scientist Jim Allison presented Nobel

Todd Ackerman | Dec. 10, 2018 | Updated: Dec. 10, 2018 7:41 p.m.

Jim Allison, the Houston scientist who identified and discovered how to unleash a brake on the immune system, was awarded the 2018 Nobel Prize in Medicine Monday, the ultimate recognition of research that's revolutionized cancer therapy.

During a ceremony at the Stockholm Concert Hall, Sweden's King Carl XVI Gustaf presented the prize to Allison, who shook his hand and then bowed, the first MD Anderson Cancer Center scientist ever to receive the now 118-year-old honor.

"Your groundbreaking research has added a fourth pillar in cancer therapy," Klas Kärre, a member of the Nobel committee, said in an introductory speech describing the achievement. "It represents a new paradigm for treatment, not directly targeting the cancer cells but rather releasing the brakes of the immune system, a landmark in the fight against cancer."

Allison, a native Texan who attended the University of Texas-Austin and plays the harmonica in two bands when not conducting immunology research, shared the award with Japan's Tasuku Honjo, who discovered a second immune system brake.

The discovery and unleashing of the brakes, known as checkpoint blockade therapy, finally realized the tantalizing promise of immunotherapy, which researchers had pursued unsuccessfully for decades. Although it doesn't benefit all cancer patients yet, it has joined surgery, radiation and chemotherapy as a mainstay of cancer treatment.

The therapy has produced cures in patients whose advanced disease was considered hopeless, particularly lung cancer and melanoma. The best known beneficiary is former President Jimmy Carter, who in 2015 said he felt he "had just a few weeks left" after he was diagnosed with melanoma that had spread to his brain. Carter is cancer free today thanks to treatment with checkpoint blockade therapy.

The therapy is currently the subject of thousands of clinical trials, most all of them efforts to extend the benefits to more people.

The 2018 Nobel is the first to recognize an achievement at once in cancer discovery *and* cancer therapy. Previous prizes for cancer research recognized either a discovery or a new therapy.

Some 15,600 people, including the Swedish Royal Family and board members of the Nobel Foundation, attended the ceremony, which was streamed live on the Nobel Prize website. It was followed by a banquet and a party with local students, known as the Nobel NightCap.

"Jim and I have experienced many occasions that have made us feel well rewarded," Honjo said at the banquet, "such as meeting cancer patients who say their lives were saved by our therapies."

Speaking on behalf of himself and Allison, Honjo added, "the development of our discovery is just beginning, as currently only 20 to 30 percent of patients respond to the immunotherapy. ... We encourage many more scientists to join us in our efforts to keep improving cancer immunotherapy. We sincerely hope this treatment will reach far and wide so that everybody on our planet can benefit from this evolutionary gift for healthy life."

The Nobel activities, which began last Thursday, will finish Wednesday.

None of the newly minted laureates spoke at the ceremony, but Allison and the other laureates gave lectures on their work at a Nobel symposium over the weekend. There, Allison explained the science and talked about his long-term hopes.

"I think that what we're going to see in the future is that checkpoint blockade is going to become a part of essentially all therapies," said Allison, 70. "That might be in combination with radiation or chemotherapy or many other things in the kinds of tumors that don't respond to checkpoints by themselves."

Allison dedicated the lecture to "the many students and fellows who have trained me and really done the work that I'll be talking about; the doctors and patients who were involved at no small risk to themselves in the early clinical trials; and finally to my partner in life and science, Dr. Padmanee Sharma, with whom much of the work was done."

Allison determined that the protein known as CTLA-4 acts as a brake to rein in the immune system, then developed a drug, Yervoy, that releases it to attack cancer cells. At the time of Allison's discovery, scientists thought CTLA-4 activated T cells, the foot soldiers of the immune system.

At the ceremony, Kärre enlisted the Royal Stockholm Philharmonic Orchestra to explain the results. To illustrate the immune system's attack when cancer exploits the brakes, a single violinist played softly and briefly, termed by Kärre as "short, slow and weak." To illustrate the attack with the brakes unleashed, the full orchestra erupted in the dramatic Prelude to Act 1 of Georges Bizet's "Carmen."

The audience applauded and Kärre said, "That was a bit different, the way (the immune system) should sound."

Allison started his career at MD Anderson in 1977, one of the first employees of a new basic science research center located in Smithville. He returned, in November 2012, with the help of a big-time grant from the Cancer Prevention and Research Institute of Texas, the state's taxpayer-funded $3 billion assault on the deadly disease.

He made his landmark discoveries about the immune system at the University of California at Berkeley, then worked with clinicians at Sloan Kettering Memorial Cancer in New York to expedite Yervoy's use in patients. Since he was lured back to MD Anderson as chairman of immunology, Allison has led the immunotherapy efforts of the center's Cancer Moon Shots initiative to accelerate the pace of research.

Previous Houston Nobel winners include Richard Smalley and Robert Curl of Rice University; Ferid Murad of the University of the Texas Health Science Center at Houston and the Houston Methodist Research Institute; and Roger Guillemin of Baylor College of Medicine.

The Nobel is the latest of dozens of prizes Allison has been awarded over the years. Previously, the most prestigious was the Lasker Award, which is often called the American Nobel. He won it in 2015.

The Nobel comes with prize money amounting to nearly $1 million, to be split by Allison and Honjo. Allison said at a news conference Thursday he'll donate the amount remaining after taxes to support other researchers working in the field and to a charity that supports schools for women.

UT NEWS

Jan 10, 2019

Bacteria Help Scientists Discover Human Cancer-Causing Proteins

A team led by researchers at The University of Texas at Austin and Baylor College of Medicine has applied an unconventional approach involving bacteria to discover human proteins that can lead to DNA damage and promote cancer. This could lead to new tests to identify people who are likely to develop cancer. Reported in the journal *Cell*, the study also proposes biological mechanisms by which these proteins can damage DNA, opening possibilities for future cancer treatments.

"This study is opening up new avenues for discoveries of novel mechanisms that protect our genomes and how their dysfunction can alter the integrity of our DNA and cause cancer," said co-corresponding author Kyle Miller, associate professor of molecular biosciences at UT Austin, who is also a member of the LIVE**STRONG** Cancer Institutes at the Dell Medical School and Baylor's Dan L Duncan Comprehensive Cancer Center.

The study's other co-corresponding authors are Susan Rosenberg and Christophe Herman at Baylor.

Mutations that cause cancer can be the result of DNA damage. External factors such as tobacco smoke and sunlight can damage DNA, but most damage seems to result from events that occur within cells and is mediated by cellular components, including proteins. Despite the importance of these internal events, they have not been studied extensively. One way human proteins can cause DNA damage is by being overproduced, which is a relatively frequent cellular event.

To uncover these DNA "damage-up" proteins in humans, the researchers took an unconventional approach. They first searched for proteins that, when overproduced, would cause DNA damage in the bacterium *E. coli*. Although bacteria and people are different, their basic biological processes are similar.

The researchers genetically modified bacteria so they would fluoresce red when DNA was damaged. Then, they overexpressed each of the 4,000 genes present in *E coli* individually and determined which ones made bacteria glow red.

"We uncovered an extensive and varied network of proteins that, when overproduced, alter cells in ways that lead to DNA damage," said Rosenberg, professor and cancer researcher at Baylor and leader of the Cancer Evolvability Program at the Dan L Duncan Comprehensive Cancer Center. Rosenberg, along with Miller, receives support from the Cancer Prevention and Research Institute of Texas (CPRIT).

When the researchers looked for human protein relatives of the DNA "damage-up" proteins they had found in bacteria, they identified 284. They determined that these human proteins are linked to cancer more often than random sets of proteins. In addition, the proteins' RNAs, an indicator of protein production, predicted mutagenesis in tumors and poor patient prognosis. When the researchers overproduced these proteins in human cells in the lab, half of the proteins triggered DNA damage and mutation.

"Some of the proteins and their mechanisms were known to be involved in cancer," said Herman, a professor at Baylor and member of the Duncan Cancer Center, "but many others were not suspected of being in the cancer-causing list."

Because the team also shed light on different mechanisms that lead to cancer-promoting DNA damage, Rosenberg said, "In the future, this finding may lead to new ways to identify people who are likely to develop cancer so that strategies to prevent it, slow it down or catch it early can be used."

"It is yet another example of the power of model organisms to uncover basic biological processes that can shine a light on how human cells and cancer work," Miller said.

The researchers still are not sure why bursts in the production of these DNA-damaging proteins occur in the first place.

The study's two co-first authors were students earning their doctorates: Jun Xia at Baylor and Liya Chiu at UT Austin.

This work was supported by the National Institutes of Health, the W.M. Keck Foundation, CPRIT, the American Cancer Society, the Dan L Duncan Comprehensive Cancer Center and the John S. Dunn Gulf Coast Consortium for Chemical Genomics.

Texas eyes another $3 billion round of cancer research bonds

By Richard Williamson

The Bond Buyer

DALLAS — Twelve years after voters created the Cancer Prevention Research Institute of Texas with $3 billion of bond authority, lawmakers are considering whether to repeat the effort.

State House Appropriations Committee chairman Rep. John Zerwas, R-Richmond, introduced House Joint Resolution 12, which would call a referendum in November to approve another $3 billion in bonds for the institute. A competing resolution would mandate that the agency devise a strategy for self-sufficiency with no new state money.

“We have seen the fruits of our investment in cancer research already," said Texas Rep. John Zerwas, who is calling for another $3 billion of cancer research and prevention bonds.

In 2007 voters approved the constitutional amendment that authorized $3 billion in general obligation bonds for the research program designed to find the causes and possible cures for cancer. The measure was seen as a boon for the state’s growing medical research economy and a strong commitment to finding a cure.

Under that amendment, bond issuances were limited to $300 million per year, with proceeds providing grants from the Cancer Prevention Research Institute of Texas, known as CPRIT. Recipients could range from established medical facilities such as the M.D. Anderson Cancer Center in Houston to start-up companies designing new treatments.

“There are great strides being made here” in Texas, Zerwas said in introducing the 2019 resolution. “We have seen the fruits of our investment in cancer research already, and we have the opportunity to see that continue over the next decade.”

During the 85th Texas Legislature in 2017, CPRIT’s sunset review date, the date at which the institute would be shuttered barring new legislative authorization, was extended by two years to 2023 to allow the agency to use all funds approved by Texas voters.

Debt service on previously issued bonds will cost Texas $120.6 million in the 2019 fiscal year that ends Aug. 31, according to CPRIT. With its bond capacity diminishing, the agency is seeking $164 million over the next two fiscal years if new bonds are not authorized.

“Without 2019 reauthorization 96,000 Texans won’t get lifesaving prevention clinical services in 254 counties as programs are dismantled for lack of funding,” CPRIT said in a prepared statement. “Advances made for Texas to become the ‘Third Coast’ for biotechnology and biomedical research would be set back. And Texas would lose $720 million per year in direct gross product and over 10,000 permanent high-quality jobs.”

In August, the Texas Public Finance Authority issued $300 million of taxable general obligation bonds for CPRIT that carried the state’s triple-A general obligation rating from four ratings agencies.

State Sen. Charles Schwertner, R-Georgetown, in January introduced Senate Bill 200, which would require CPRIT to become self-sufficient when state funding runs out.

Schwertner, an orthopedic surgeon, is chairman of the Senate Committee on Health and Human Services that sets public health policy for the state, regulating physicians and other health professions, and providing legislative oversight of the state's health-related agencies. Schwertner is also a member of the Senate Committees on Finance, Administration, Business and Commerce and State Affairs.

In 2013, Schwertner was also named to the 12-member Sunset Advisory Commission that is charged with providing a comprehensive periodic review of more than 150 state agencies. In 2015, Schwertner introduced a measure similar to his current bill that would have forced CPRIT off taxpayer funding.

CPRIT spokesman Chris Cutrone said agency officials have studied Schwertner's proposal since its 2015 introduction.

"Self-sufficiency is not a feasible solution because Texas' portion of grantee profits will not be at a level necessary for many years to serve as a sustainable, predictable funding source," Cutrone said.

"Nowhere in law or the constitution is self-sufficiency contemplated for CPRIT. Had it been, self-sufficiency would have radically altered our research investment strategy. We would have given no prevention grants, minimal if any academic research grants, and instead of funding early stage translational work in product development we would have invested in late stage Phase 3 and 4 clinical trials thereby competing with the private sector."

CPRIT's longstanding investments are improving outcomes in childhood cancer, the agency says.

"With continued support, Texas is poised to be the world leader in childhood cancer research," its officials say.

Although cancer researchers can claim some advances in the 40-year-old war on cancer, some experts acknowledge that much of the progress has come from prevention efforts such as the campaign against smoking.

In her 2012 book "A World Without Cancer," Dr. Margaret Cuomo, sister of New York Gov. Andrew Cuomo, wrote that the National Cancer Institute alone has spent about $90 billion on research and treatment.

"Some 260 nonprofit organizations in the United States have dedicated themselves to cancer — more than the number established for heart disease, AIDS, Alzheimer's disease, and stroke combined," Cuomo wrote. "Together, these 260 organizations have budgets that top $2.2 billion."

Cuomo's book advocates improved coordination among government and academic research efforts and an elimination of unnecessary bureaucracy.

In July, the Cancer Prevention Institute of California, a San Francisco Bay Area independent, nonprofit cancer research institute, announced that it would disband as an independent cancer research institute 44 years after its founding.

Over the years, CPIC researchers have moved to other institutions, including the University of California at San Francisco and Stanford University.

“While CPIC will no longer operate as the independent organization that has existed for 44 years, we take great comfort in knowing CPIC’s legacy will live on since all of CPIC’s scientific and community education programs are being preserved, and will carry on either at UCSF or at Stanford,” said Matt O’Grady, interim chief executive of CPIC. “We’re also thankful very few jobs will be lost as a result.”

In Texas, CPRIT survived a political scandal shortly after its creation. The institute was forced to defend its grant-making processes after a company funded by a top donor to then Gov. Rick Perry, now U.S. Energy secretary, was flagged for receiving money without passing through the usual screening process.

Perry was the chief advocate for creating CPRIT.

In 2012, the Dallas Morning News reported CPRIT had awarded an $11 million grant to Peloton Therapeutics, a biotech company, without required scientific review. A major investor in Peloton was also a top contributor to Perry, according to news reports.

The Travis County public integrity unit, which at the time investigated public corruption, opened an investigation into CPRIT officials. Perry later vetoed funding for the public integrity unit, claiming that he did so to force the district attorney to resign after a conviction for driving while intoxicated. That led to a 2014 felony indictment of Perry for abuse of official capacity and coercion of a public servant. Those charges were later dismissed by the Texas Court of Criminal Appeals.

Amid the controversy, state leaders placed a moratorium on new CPRIT grants in December 2012, and when lawmakers convened for the 2013 legislative session, they restructured the agency’s grant award processes and made changes to improve oversight and prevent conflicts of interest. In October, the moratorium was lifted.

Schwertner’s Senate Bill 197 that failed to pass in the 2015 session would have ended state support for CPRIT by 2021.

“In the face of so many other competing funding priorities that legislators must consider, it is prudent for the institute to prepare to rely on other funding sources,” Schwertner said as he introduced the bill.

With its future in doubt, CPRIT must plan for two possible outcomes in the current session.

“Although CPRIT plans to fully commit the $3 billion in bond proceeds prior to the agency’s sunset, some portion of the bonds will remain for the state to issue for grant disbursements,” Cutrone said. “The state’s plan for staff and resources necessary to monitor the drawdown of grant funds post 2023 and coordinate with the Texas Public Finance Authority and the Bond Review Board is a topic that will be discussed in the 2023 legislative session.”

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

To:	OVERSIGHT COMMITTEE MEMBERS
From:	KRISTEN DOYLE, INTERIM CHIEF PRODUCT DEVELOPMENT OFFICER
Subject:	PRODUCT DEVELOPMENT PROGRAM UPDATE
Date:	FEBRUARY 13, 2019

Product Development Research FY 2018 Cycle 2

After evaluating additional information from two applicants pending final award decisions in the second award cycle of FY 2018, CPRIT's Product Development Review Council (PDRC) chose not to recommend either application for an award.

Product Development Research Applications FY 2019 Cycle 1

CPRIT received 38 applications for the Product Development FY 2019 Award Cycle 1 by the August 8, 2018, deadline. After peer review and in-person presentations by the applicants, the PDRC convened January 11, 14, and 22 to conduct the due diligence review meeting for nine applications from the 19.1 award cycle.

The PDRC and the PIC recommend that the Oversight Committee approve five applications for grant awards totaling $30.7 million. The PDRC decided not to make final award recommendations for two applications in the 19.1 cycle, pending review of additional information from the applicants. If the PDRC decides to recommend awards to either of the two companies still under review, the Oversight Committee may take up the recommendation at the May or August meeting.

FY 2019 Cycle 2 Product Development Research RFAs

CPRIT released three RFAs on December 5, 2018, and accepted applications through January 30. Applicants submitted 28 proposals, which are currently undergoing administrative review. Initial peer review will take place March 18-19 and applicants that the peer review panel invites to make in-person presentations will do so April 15-18. Following due diligence, the Chief Product Development Officer will present the PDRC's recommendations to the PIC and Oversight Committee at the August Oversight Committee meeting.

PO Box 12097 | Austin, Texas 78711 | PH: 512-463-3190 | F: 512-475-2563 | www.cprit.state.tx.us

Review Cycle 19.2 Application Data by Mechanism

Mechanism	Applications Received	Funds Requested
Texas Company	5	$73.8M
Relocation Company	9	$108.8M
Seed Company	14	$37.8M
TOTAL	**28**	**$220.3M**

FY 2020 Product Development Research RFAs

With the Oversight Committee's approval, the Product Development Research Program proposes to release the TXCO, RELCO and SEED RFAs (described below) in FY 2020. These are the same RFAs that CPRIT released in FY 2019. CPRIT plans to release the proposed RFAs on May 30, 2019, with the Chief Product Development Officer presenting award recommendations at the February 2020 Oversight Committee meeting.

Pursuant to the plan approved in January 2018 by the Oversight Committee for fiscal years 2020 and 2021, CPRIT will have only one award cycle in each of the next two years. If the legislature allocates more grant funding to CPRIT in the current legislative session, the Product Development Research Program will be prepared to conduct a second review cycle in fiscal year 2020, likely using the same three RFAs as the first review cycle.

- *Texas Company Product Development Research Award*
  This award supports early-stage "start-up" and established companies in the development of innovative products, services, and infrastructure with significant potential impact on patient care. The proposed project must further the development of new products for the diagnosis, treatment, or prevention of cancer; must establish infrastructure that is critical to the development of a robust industry; or must fill a treatment or research gap. Companies must be headquartered in Texas.
  Award: Maximum amount $20M; Maximum duration of 36 months

- *Relocation Company Research Award*
  This award supports early-stage "start-up" and established companies in the development of innovative products, services, and infrastructure with significant potential impact on patient care. The proposed project must further the development of new products for the diagnosis, treatment, or prevention of cancer; must establish infrastructure that is critical to the development of a robust industry; or must fill a treatment or research gap. Companies must relocate to Texas upon receipt of award.
  Award: Maximum amount $20M; Maximum duration of 36 months

- *Seed Award for Product Development Research*
  The award supports projects that are earlier in their development timeline than CPRIT's two other Product Development Awards, the Texas Company Award (TXCO) and the Company

Relocation Award (RELCO). The proposed project must further the development of new products for the diagnosis, treatment, or prevention of cancer; must establish infrastructure that is critical to the development of a robust industry; or must fill a treatment or research gap. Company applicants must be headquartered in Texas or be willing to relocate to Texas upon receipt of award.
Award: Maximum amount of $3M; Maximum duration of 36 months.

2018 Annual Report
CPRIT Advisory Committee on Childhood Cancer (ACCC)
Submitted to the CPRIT Oversight Committee
February 2019

I. Introduction

The CPRIT Advisory Committee on Childhood Cancer (ACCC) convened via teleconference approximately quarterly during the past year to review membership of the Advisory Committee, to discuss CPRIT-funded childhood cancer research progress, and to formulate recommendations for the CPRIT Oversight Committee on priority areas for funding of research, prevention/survivorship, and product development in childhood cancer.

Although CPRIT has broad-based goals to expedite innovation in cancer research and product development, and to enhance access to evidence-based cancer treatment and prevention programs across the state, the ACCC and childhood cancer advocacy groups in Texas commend CPRIT leadership for continuing to maintain childhood cancer research as a high priority. As outlined in detail, this has been evidenced by a remarkable level of grant funding across the full spectrum of the CPRIT research portfolio and extending throughout Texas. The ACCC members also applaud CPRIT leadership for its ongoing focus on funding only the highest caliber cancer research as guided by its notably robust, scientific peer-review process. Indeed, that CPRIT Scholars in 2018 were included among Nobel Prize winners and members of the United States National Academy of Medicine underlines how the exceptional contributions of CPRIT-funded researchers are helping to bring game-changing breakthroughs to the clinic for cancer patients – including children – across Texas and throughout the world.

II. Progress to date

With the unwavering leadership of Dr. James Willson as Chief Scientific Officer, CPRIT continues to enable remarkable childhood cancer research efforts in Texas, and that success can be measured in a number of ways.

First, since its inception, CPRIT has funded 152 research projects focused on childhood cancer with grant funding exceeding $250 million dollars, representing approximately 12% of the total CPRIT funding. Critically, the funded grants focus on a wide range of child cancer types and important clinical problems. Notable examples in this past year include Independent Investigator Research Awards focused on childhood brain tumors, leukemia, and bone and soft tissue sarcomas – all diseases for which better understand of disease biology can lead to breakthroughs in the clinic – and these grants were awarded to institutions across the state. Obviously, the ultimate impact of childhood cancer research measured by life-years for survivors of childhood cancer is dramatic.

Success in the childhood cancer research program can also be measured by publication of peer-reviewed scientific manuscripts, which disseminate the new knowledge world-wide, and in new clinical research studies. In 2018 alone, nearly 30 scientific papers reported new findings from CPRIT-funded childhood cancer research efforts. These findings were published in some of the top scientific and biomedical research journals, including *Nature*, *Cell Reports*, *Elife*, *Development*, *Nature Communications*, and the *Journal of Clinical Investigations*. Perhaps more importantly than just publications, CPRIT funding in 2018 has enabled active clinical research trials for childhood cancer patients in Texas. Representative examples include testing a new type of therapy for neuroblastoma (Texas Tech University HSC); testing new ways to enable "precision medicine" by identifying therapeutic targets in childhood leukemia (UT MD Anderson Cancer Center) and better risk stratification tools in bone cancer (UT Southwestern Medical Center); and studying childhood cancer prevention strategy through vaccination (UTHSC Houston). CPRIT funding to support industry partners also led studies of new treatments for Ewing sarcoma (Salarius Pharmacuticals LLC) and forms of leukemia (Bellicum Pharmaceuticals). Hence, the CPRIT portfolio of childhood cancer research is directly influencing the care of children with cancer in our state.

Third, CPRIT funding is playing an additional, critical role in enabling Texas' leadership in childhood cancer research through their Core Facilities Support Awards focused on childhood cancer. New CPRIT-funded Cores in 2018 are particularly insightful and forward thinking as they are focused on regenerative medicine, an emerging concept in medicine, and also generating sophisticated computational and informatics infrastructure that will be enable more sophisticated analyses of "big data" stemming, for example, from wedding genomics data to electronic health records. The importance of these developing these types of Data Resources or Data Cores for childhood cancer research cannot be overstated, and CPRIT funding positions Texans to lead the nation in this area.

Finally, CPRIT recruitment awards continue to represent a particularly noteworthy mechanism to draw new scientific resources to Texas. Ten childhood cancer researchers have already been recruited here, including Dr. Sean Morrison, an Investigator in the Howard Hughes Medical Institute and a new member of the US National Academy of Medicine, who was the first CPRIT recruit in childhood cancer. Two new Texas researchers, John Powers (UT Austin) and Kenneth Chen (UT Southwestern) will bring their research in childhood brain tumors and kidney cancer to our state. Obviously, the short and long-term impact of these these types of recruits to the field of pediatric oncology can be substantial, especially as their new research teams can provide synergy with existing researchers in Texas.

A project by project summary of the impact of the funded projects on the field of pediatric oncology and the resultant publications and clinical trials is shown in Appendix A.

III. The ACCC recommends that CPRIT continue to retain childhood cancer-focused funding in three major areas:

1) **Investigator-Initiated Research**
    a. Support for clinical and translational research carried out by individual investigators as well as by collaborative teams of investigators should remain a high-priority. Maintaining the broad portfolio of Research Awards that includes Cancer in Children and Adolescents, Clinical Translation, and Prevention and Early Detection, is deemed by the ACCC to be quite important.
2) **Core Facility Support Awards**
    a. The ACCC recommends that CPRIT continue to prioritize initiatives for core facilities to support childhood cancer. CPRIT funding to support the Texas Patient Derived Xenograft Facility, Adolescent and Childhood Cancer Epidemiology and Susceptibility Service for Texas, Individualized Pediatric Tumor Analysis Center of Texas, Pediatric Cancer Data Core, and Pediatric Solid Tumors Comprehensive Data Resource Core programs all are viewed as outstanding examples where this type of funding can have broad reach across the state, while also providing infrastructure to close important scientific gaps.
    b. The ACCC recognizes that importance of a similar type of "Core" that could provide clinical research infrastructure to enable Texas-wide clinical trials for childhood cancer. Indeed, as previous CPRIT-funding laboratory-based research programs are progressing, this type of platform will be increasingly important as that work is extended to the clinic, to improve childhood cancer care across the state.
3) **Recruitment Awards**
    a. As outlined above, the recruitment award program has brought high-quality, childhood cancer researchers to Texas. The ACCC recommends that this program be continued.
4) **Multi-Investigator Research Awards**
    a. The ACCC members feel that Multi-Investigator Research Awards in childhood cancers (liver cancer, bone cancer, soft tissue sarcoma) have met with significant success with respect to forging inter-institutional collaborations and propelling scientific discovery toward the clinic. It is suggested that CPRIT continue a funding mechanism that enables/prioritizes research funding opportunities inter-institutional collaborations, especially where such collaborations enhance scientific discovery and clinical translational potential to a greater geographic area.

IV. Prevention Portfolio

Childhood cancer survivorship and prevention

The ACCC members applaud the recent funding opportunities focused on cancer prevention services, including services to rural and medically-underserved areas. The implementation of known cancer prevention *services* (e.g., HPV vaccination, tobacco use prevention) for children and young adults is, of course, important. Beyond providing services, the ACCC has previously recommended that a cancer prevention research focus could include studying cancer prevention/control approaches in cancer pre-disposition syndromes, and childhood cancer survivors at high risk of second malignant neoplasm.

However, the ACCC also recommends that the prevention portfolio be expanded to include the study of means to improve the health of childhood cancer survivors and how best to implement those services, especially in rural areas and underserved populations. The increased survival rates for childhood cancer patients justifies such an initiative. Previously suggested focal points include understanding and treating long-term side effects of treatment; improving quality of life in numerous realms, including cognitive outcomes, education/employment, and fertility preservation.

V. Product Development Portfolio

Commercial Development of Diagnostics and Therapeutics for Childhood Cancer

Given the general paucity of pediatric cancer drug development programs, and the rarity of the commercial entities funded by CPRIT to focus on childhood cancer, the ACCC continues to recommend exploration and discussion of innovative ways to facilitate and encourage commercial development of drugs and diagnostics for childhood cancer.

VI. Summary

The ACCC is continues to be grateful to CPRIT leadership for its commitment cancer research and prevention programs that are focused on childhood cancer. Recent FDA approval of new childhood cancer therapies related to cell-based immunotherapy and molecularly-targeted therapies for cancers with a specific type of genetic rearrangement, illustrate the life-saving impact of such breakthroughs in childhood and adult cancer. CPRIT funding mechanisms continue to catalyze collaboration between clinical and laboratory investigators across Texas, to benefit children with cancer as well as their families. The essentially unprecedented commitment by CPRIT and the state of Texas to childhood cancer research has accelerated research discovery and translation, and the value of that commitment is increasingly recognized and applauded across the nation.

APPENDIX A

CPRIT Funded Childhood and Adolescent Cancer Research

BIBLIOGRAPHY 2018

RP120685-AC
Molecularly Targeted Therapy for Soft Tissue Sarcoma in Texas
Multi-Investigator Research Awards
PI: Stephen Skapek, M.D.
The University of Texas Southwestern Medical Center

Sarcoma, a cancer arising from soft tissues like muscle, fat, and connective tissue holding other tissues together, afflicts thousands across North America. Our proposal focuses on two types of sarcoma that commonly strike children and young adults: soft tissue sarcoma (STS) and Ewing sarcoma family tumor (ESFT). New therapy is desperately needed because less than 20% of the large proportion of patients with disseminated STS/ESFT will survive 5 years after diagnosis. This survival rate has not improved in many years, despite the use of aggressive treatments incorporating surgery, radiation and chemotherapy associated with life-threatening or life-changing side effects. Over the last 10 years, new molecular biology and computing tools have fostered detailed analyses of genetic material in cancer. It was hoped that such studies would quickly reveal genetic mutations that could be attacked using new therapeutics designed to hit those specific molecular targets. Sadly, it has become increasingly clear that cancer specimens harbor a vast number of genetic abnormalities. Hence, the emerging genetic information has only rarely enabled the next, critical step: the development of more effective therapy.

We intend to close this gap in two phases. First, we will use sophisticated computation tools and laboratory models to sift through the genetic abnormalities that we will uncover in STS/ESFT to identify those that actually drive sarcoma growth. Second, we will establish the capacity to detect the key genetic changes – called “actionable” mutations – in STS/ESFT across Texas in “real-time” so that physicians can use the information to choose the molecularly targeted drugs most likely to work in an individual sarcoma patient. Our success over the next several years will revolutionize the care of children and young adults with STS and ESFT, improving their survival by giving therapy that is “personalized” to meet their needs.

- Laetsch TW, Roy A, Xu L, Black JO, Coffin CM, Chi YY, Tian J, Spunt SL, Hawkins DS, Bridge JA, Parsons DW, Skapek SX. Undifferentiated Sarcomas in Children Harbor Clinically Relevant Oncogenic Fusions and Gene Copy-Number Alterations: A Report from the Children's Oncology Group. Clin Cancer Res. 2018 Aug 15;24(16):3888-3897. doi: 10.1158/1078-0432.CCR-18-0672. Epub (2018) Apr 24. PubMed PMID: 29691299

- Xu L, Zheng Y, Liu J, Rakheja D, Singleterry S, Laetsch TW, Shern JF, Khan J, Triche TJ, Hawkins DS, Amatruda JF, Skapek SX. "Integrative Bayesian Analysis Identifies Rhabdomyosarcoma Disease Genes." Cell Rep. 2018 Jul 3;24(1):238-251. doi: 10.1016/j.celrep.2018.06.006. PubMed PMID: 29972784.

- Kendall GC, Watson S, Xu L, LaVigne CA, Murchison W, Rakheja D, Skapek SX, Tirode F, Delattre O, Amatruda JF. PAX3-FOXO1 transgenic zebrafish models identify HES3 as a mediator of rhabdomyosarcoma tumorigenesis. Elife. 2018 Jun 5;7. pii: e33800. doi: 10.7554/eLife.33800. PubMed PMID: 29869612; PubMed Central PMCID: PMC5988421.

- Gorthi A, Romero JC, Loranc E, Cao L, Lawrence LA, Goodale E, Iniguez AB, Bernard X, Masamsetti VP, Roston S, Lawlor ER, Toretsky JA, Stegmaier K, Lessnick SL, Chen Y, Bishop AJR. EWS-FLI1 increases transcription to cause R-loops and block BRCA1 repair in Ewing sarcoma. Nature. 2018 Mar 15;555(7696):387-391. doi: 10.1038/nature25748. Epub 2018 Mar 7. Erratum in: Nature. 2018 Jun 27;. PubMed PMID: 29513652; PubMed Central PMCID: PMC6318124.

RP140258
The Intersection between Childhood Cancer and Congenital Anomalies: Identifying Novel Cancer Predisposition Syndromes
Individual Investigator Research Awards

PI: Philip Lupo, M.D.
The University of Texas M.D. Anderson Cancer Center

One of the strongest risk factors for childhood cancer is being born with a birth defect. This risk is present not only among children with major congenital malformations, but also among those with minor birth defects. In fact, more than 10% of childhood cancers may be attributed to having a birth defect. Exploring the intersection of birth defects and childhood cancer is likely to provide valuable insights into what causes cancer and may also provide information that can be used to improve screening strategies in cancer prevention clinics. As an estimated 7.9 million children worldwide are born with a congenital malformation each year, the public health implications of identifying why some of these children develop cancer are substantial. In spite of these recognized patterns, much work remains in discovering novel birth defect-childhood cancer combinations and in characterizing cancer predisposition syndromes. In practice, identifying birth defect-childhood cancer patterns is challenging because large population-based studies with sufficient numbers of birth defects are necessary to allow for meaningful estimation of childhood cancer risks. Because of this, we will leverage high-quality data from the Texas Cancer and Birth Defects Registries with information on over 7 million births to: 1) find novel birth defect-childhood cancer associations and 2) create a family-based study for genomic analyses. We will then utilize state-of-the-art techniques in DNA sequencing available at the Human Genome Sequencing Center at Baylor College of Medicine to thoroughly study all of the genes from families with individuals with birth defects and childhood cancer. Our overall goal is to identify novel genes which when altered increase the risk of

childhood cancer. This is a unique and timely opportunity to aid in the discovery of novel cancer susceptibility syndromes. Children with these disorders will benefit from targeted cancer screening and surveillance programs.

- Agopian AJ, Evans JA, Lupo PJ. Analytic Methods for Evaluating Patterns of Multiple Congenital Anomalies in Birth Defect Registries. Birth Defects Res. 2018 Jan 15;110(1):5-11. doi: 10.1002/bdr2.1115. Epub 2017 Sep 19. Review. PubMed PMID: 28925590.

RP150032
Developing New Combinatory Therapies for Pediatric High-Grade Glioma
Individual Investigator Research Awards for Cancer in Children and Adolescents

Xiao-Nan Li, M.D.
Baylor College of Medicine

The five-year survival in children with high grade glioma is still less than 10%. Recent advances of genomic sequencing methods have made it possible to discover nearly all gene mutations in pediatric gliomas. The objective of this application is therefore to develop new combinatory therapies that will selectively target those mutations critical for tumor cell survival. Since most of the tumors have many different mutated genes, we have designed a new “anchor-probe” strategy to selectively and efficiently target multiple abnormalities. Based on the genetic concept known as “synthetic lethality”, we hypothesize that simultaneous perturbation of two (or more) mutated genes can result in a deadly combination (i.e. kill the tumor cells). We plan to use “anchor” drugs to target recurring mutations found in pediatric gliomas and “probe” drugs, identified through high throughput screening from a large series of FDA-approved drugs and investigational agents, to launch a 2nd strike. We have established a large panel of patient-derived orthotopic xenograft (PDOX) models that replicate the pathologies and maintain gene mutations of this deadly disease. In this proposal, we will team up with the CPRIT-funded Texas Screening Alliance for Cancer Therapeutics to develop novel “anchor-probe” combinations for critical genetic mutations, confirm their therapeutic efficacy in our 16 PDOX models, the first and the largest panel in the world, and understand the mechanisms of cell killing and drug resistance in these tumors. Our goal is to establish strong preclinical rationale for these new combinatory therapies so that clinical trials can be initiated within 1-3 years. Completion of our studies will help to bridge the gap between cancer genomics findings and new effective therapies and will facilitate a paradigm shift from “one-size-fit-all” treatment to “customized” target therapies for children with high grade glioma.

- Kogiso M, Qi L, Braun FK, Injac SG, Zhang L, Du Y, Zhang H, Lin FY, Zhao S, Lindsay H, Su JM, Baxter PA, Adesina AM, Liao D, Qian MG, Berg S, Muscal JA, Li XN. Concurrent Inhibition of Neurosphere and Monolayer Cells of Pediatric Glioblastoma by Aurora A Inhibitor MLN8237 Predicted Survival Extension in PDOX Models. Clin Cancer Res. 2018 May 1;24(9):2159-2170. doi: 10.1158/1078-0432.CCR-17-2256. Epub 2018 Feb 20. PubMed PMID: 29463553; PubMed Central PMCID: PMC6052861

RP150081
Genetic susceptibility to testicular germ cell tumors
Individual Investigator Research Awards for Cancer in Children and Adolescents
Jason Heaney, Ph.D.
Baylor College of Medicine

Testicular germ cell tumors (TGCTs) are the most frequent solid tumor diagnosed in boys and young men. TGCTs result from defects in the development of embryonic male germ cells, which normal develop into sperm. TGCTs are treatable by surgery, radiation, and chemotherapy. However, current treatments cause long-term side effects such as mental impairments and infertility. TGCTs may also spread to other organs if not detected early or completely removed. In addition, many TGCTs are resistant to otherwise effective treatment options. Thus, improvements in early diagnosis and treatment remain important, and the social, emotional, and medical costs remain high. The likelihood of an individual developing a TGCT is significantly increased when a relative also has a TGCT. Studies of human TGCTs have begun to identify genes associated with inherited risk. However, these associations only contribute to a small portion of total risk. Additionally, studies to characterize how these genes contribute to TGCT risk are hindered by the limited availability of human tumor samples and the initiation of TGCTs during embryonic life. In this application, we use mice that spontaneously develop TGCTs to model the disease seen in humans and to characterize new inherited traits, or genes, that contribute to the complexity surrounding the genetic component of TGCTs. These studies are possible due to the similarities in TGCT inherited risk factors and disease progression between mice and humans. We propose studies to demonstrate that three key genes participate in a web of complex interactions that disrupt the normal development of male embryonic germ cells in mice. We believe that in germ cells, misregulation or misexpression of these genes, and their inappropriate interactions with other genes, transform the germ cells to become seeds of tumor growth. Additionally, we propose studies to determine whether these genes are potential treatment targets for TGCTs in young boys and adolescents.

- Dawson EP, Lanza DG, Webster NJ, Benton SM, Suetake I, Heaney JD. Delayed male germ cell sex-specification permits transition into embryonal carcinoma cells with features of primed pluripotency. Development. 2018 Mar 15;145(6). pii: dev156612. doi: 10.1242/dev.156612. PubMed PMID: 29545285.

RP150334
Personalized Functionalization of Pediatric High Grade Glioma
Individual Investigator Research Awards for Cancer in Children and Adolescents
Benjamin Deneen, Ph.D.
Baylor College of Medicine

A major effort in cancer research is focused on identifying genes directly responsible for promoting cancer progression (referred to here as "drivers"). The identification of driver genes and characterization of their function has been the moving force behind much of the recent progress in cancer treatment. Driver identification is particularly important for aggressive cancers such as pediatric high-grade glioma (PHGG), which represents 10% of all pediatric brain tumors. Most children diagnosed with PHGG receive a dismal prognosis, as the disease carries a 5-year survival rate of <5%. Recent studies at the Baylor College of Medicine characterized the full spectrum of gene mutations present within PHGG tumor genomes. The challenge now is to develop efficient means to identify which of these mutant genes are directly responsible for PHGG. Discovery of such driver genes is a significant challenge given their large number and the fact that their activity is shaped by tumors' immediate surrounding environment within the body. To identify PHGG drivers, we will use a novel screening platform that employs (1) our robotics-driven collection of over 32,000 human genes, (2) an innovative strategy that enables rapid modeling of barcoded mutant genes based on the genomes of individual PHGG patient tumors and (3) a driver screening system for delivering these cancer gene candidates directly to the developing mouse brain. We will use these technologies to identify functional PHGG driver genes, providing unprecedented insight into driver gene networks responsible for this fatal disease. Moreover, these studies will illuminate new drug targets desperately needed by PHGG patients with no other effective treatment options. Our ultimate goal is to scale these efforts into a personalized clinical trial pipeline that would provide functional relevance of patient's tumor genome at the time of biopsy that would facilitate decisions on individualized patient therapy.

- Kfoury N, Sun T, Yu K, Rockwell N, Tinkum KL, Qi Z, Warrington NM, McDonald P, Roy A, Weir SJ, Mohila CA, Deneen B, Rubin JB. Cooperative p16 and p21 action protects female astrocytes from transformation. Acta Neuropathol Commun. 2018 Feb 20;6(1):12. doi: 10.1186/s40478-018-0513-5. PubMed PMID: 29458417; PubMed Central PMCID: PMC5819173.

RP150343
An ultra-sensitive nanomagnetic sensor for the early detection of anaplastic large cell lymphoma
Individual Investigator Research Awards for Cancer in Children and Adolescents
Richard Willson, Ph. D
University of Houston

Early detection of cancer saves lives, costs, and suffering. Many cancers have 5-year survival rates near 80-90% when caught early, but much poorer outcomes when detected later. Advances in genomics and cell biology increasingly are identifying molecules whose presence in the body is a clear signal of cancer. We propose to advance the commercialization of an ultra-sensitive platform sensing technology for improving the detection of these diagnostically-informative molecules. We have proof-of-concept of the sensor, which was developed under an NIH grant funded in the top 2% of competing proposals. In this work we will advance the development in the sensing technology, and demonstrate its application to earlier, less-invasive diagnosis of anaplastic large cell lymphomas (ALCL). ALCL is the most common childhood T-cell lymphoma and the second most common T-cell lymphoma in adults. Especially in children, ALCL usually is characterized by a distinctive protein, NPM-ALK, which is exceptionally stable and accumulates in lymphoma cells. Ultrasensitive detection could allow earlier diagnosis, diagnosis from blood samples instead of invasive biopsies, better treatment monitoring, and earlier detection of recurrent disease. The PI leads Diagnostics for an NIH Center of Excellence, and is highly experienced in biodetection and technology-translation. We have miniaturized sensors to the nanometer scale, thus increasing sensitivity. There is a realistic prospect of detecting single molecules with sensor arrays that will be corrosion-resistant, low-fouling, and cheap enough to be disposable, like a USB thumb drive. Our team has worked together for years, and covers the needed range of magnetic nano-fabrication, biochemical, and clinical expertise. Collectively, we have started several successful companies, have ca. 100 patents, and have diagnosed hundreds of cases of ALCL.

- Jacinto MJ, Trabuco JRC, Vu BV, Garvey G, Khodadady M, Azevedo AM, et al. (2018) Enhancement of lateral flow assay performance by electromagnetic relocation of reporter particles. PLoS ONE 13(1): e0186782. https://doi.org/10.1371/journal.pone.0186782

RP150445
Ewing's sarcoma, a homologous recombination defective disease
Individual Investigator Research Awards for Cancer in Children and Adolescents
Alexander Bishop, Ph.D.
The University of Texas Health Science Center at San Antonio

Ewing's sarcoma occurs in children and young adults. The standard treatment, that effective 70% of the time, is a mixture of toxic chemotherapeutics and surgery. The toxicity in children is a concern since any damaging effects last a lifetime. Further, no successful alternatives exist beyond this first line treatment. Targeted therapy with less toxicity would be a major benefit, but requires a better understanding of Ewing's sarcoma. We discovered that Ewing's sarcoma has a defect in a DNA repair pathway called homologous recombination. This is the same kind of defect found in BRCA1 deficient breast cancer. Those cancers are sensitive to PARP1 inhibitors and so is Ewing's sarcoma. We believe that this opens an opportunity to develop more targeted therapy strategies based on understanding how homologous recombination has been compromised. We examined the genes altered in Ewing's sarcoma, particularly the EWSR1 gene, and found that this gene is also necessary for homologous recombination. Interestingly, the protein made by this gene is involved in RNA transcription, the process of translating the DNA code into RNA, which is then used to make proteins in the cell. If this process is broken in some way, it can cause problems for the machinery that is involved in duplicating the DNA as cell grow and divide. We therefore propose to examine these processes in Ewing's sarcoma and in cells where we deplete EWSR1. If we are correct, then these studies will provide novel insight into Ewing's sarcoma and provide novel therapeutic strategies that are potentially less toxic to the cell. Further, since we know from BRCA1 studies some of the mechanisms that can circumvent a homologous recombination defect we can test if the same are altered in chemoresistant Ewing's sarcoma. Based on this we will test whether there are second line targeted therapies that can take advantage of these secondary changes and make otherwise resistant Ewing's sarcoma sensitive to treatments again.

- Countryman P, Fan Y, Gorthi A, Pan H, Strickland J, Kaur P, Wang X, Lin J, Lei X, White C, You C, Wirth N, Tessmer I, Piehler J, Riehn R, Bishop AJR, Tao YJ, Wang H. Cohesin "SA2 is a sequence-independent DNA-binding protein that recognizes DNA replication and repair intermediates". J Biol Chem. 2018 Jan 19;293(3):1054-1069. doi: 10.1074/jbc.M117.806406. Epub 2017 Nov 24. PubMed PMID: 29175904; PubMed Central PMCID: PMC5777247.

- Gorthi A, Romero JC, Loranc E, Cao L, Lawrence LA, Goodale E, Iniguez AB, Bernard X, Masamsetti VP, Roston S, Lawlor ER, Toretsky JA, Stegmaier K, Lessnick SL, Chen Y, Bishop AJR. EWS-FLI1 increases transcription to cause R-loops and block BRCA1 repair in Ewing sarcoma. Nature. 2018 Mar 15;555(7696):387-391. doi: 10.1038/nature25748. Epub 2018 Mar 7. Erratum in: Nature. 2018 Jun 27;. PubMed PMID: 29513652; PubMed Central PMCID: PMC6318124.

RP160237
A novel epigenetic reader as therapeutic target in MLL-translocated pediatric leukemias
Individual Investigator Research Awards for Cancer in Children and Adolescents
Michelle Barton, Ph.D.
The University of Texas M.D. Anderson

Cancer is the leading cause of disease-related death among children and adolescents in the United States. Leukemias, cancers of the bone marrow and blood, are the most common childhood cancers, that account for ~30% of all cancers in children versus ~2% in adult. The most prevalent leukemia types in children are acute lymphoblastic leukemia (ALL) and acute myeloid leukemia (AML). Despite remarkable improvement in the treatment outcomes over the past decades, a high-risk subgroup of ALL patients that bear translocations involving the MLL (mixed-lineage leukemia) gene are particularly associated with poor response to standard treatments and dismal prognosis. The MLL gene is located on chromosome 11q23. Rearrangements of the MLL gene are associated with aggressive acute leukemias, both lymphoblastic and myeloid. Up to 80% of infant ALL and 35-50% of infant AML are characterized by MLL rearrangement. However, the development of effective therapies for this subtype of aggressive fatal disease is still in urgent need.
In leukemias, MLL is found to fuse with >70 partners, among which the most frequent fusion partners are components of two protein complexes: the super elongation complex and the DOT1L complex. These fusions are believed to share a common pathway by “hijacking” these protein complexes to promote aberrant activation of MLL-fusion target genes. Nevertheless, detailed regulation of the MLL-fusions and the associated proteins and their roles in leukemogenesis are still not clear. Our preliminary discovery of the ENL and AF9 YEATS domains in the recognition of histone acetylation suggest that ENL and AF9 may function as epigenetic readers within these complexes. In this study, we will determine whether the recognition of histone acetylation by the YEATS domain is essential for the growth, survival, and tumorigenesis of the MLL rearranged leukemias. The proposed study will likely provide the YEATS domain as a potential therapeutic target.

- Hsu CC, Shi J, Yuan C, Zhao D, Jiang S, Lyu J, Wang X, Li H, Wen H, Li W, Shi X. Recognition of histone acetylation by the GAS41 YEATS domain promotes H2A.Z deposition in non-small cell lung cancer. Genes Dev. 2018 Jan 1;32(1):58-69. doi: 10.1101/gad.303784.117. Epub 2018 Feb 1. PubMed PMID: 29437725; PubMed Central PMCID: PMC5828395.

RP160249
DIS3L2 in Childhood Wilms Tumor: Mechanism to Medicines
Individual Investigator Research Awards for Cancer in Children and Adolescents
Joshua Mendell, M.D.
The University of Texas Southwestern Medical Center

Wilms tumor is the most common kidney cancer in children and one of the most common childhood cancers overall. While most children with Wilms tumors can be treated successfully with combinations of surgery, radiation and chemotherapy, there are some with more aggressive tumors who unfortunately cannot be cured with current treatments. Furthermore, survivors of Wilms tumor therapy often later develop significant health problems, including hearing loss, kidney dysfunction, heart failure and secondary cancers. A better approach would be to devise treatments that are targeted to the specific abnormalities in the cancer cells that cause them to grow out of control. Such treatments have the potential to be both more effective and less toxic than current therapies. A few Wilms tumor mutations (i.e., changes in the tumor DNA sequence) are known, including mutations that occur in a gene called DIS3L2. This gene is frequently mutated in sporadic Wilms tumors, and children that inherit mutations in DIS3L2 develop a disease called Perlman syndrome, which is associated with overgrowth, kidney abnormalities including Wilms tumors, and early death. Nevertheless, how mutation of DIS3L2 causes Perlman syndrome and Wilms tumors is unknown. Using genetically engineered mice, we have discovered that DIS3L2 regulates a major growth-promoting pathway within kidney cells, which likely explains how mutations in this gene give rise to Perlman syndrome and Wilms tumors. In this application, we propose to apply cutting-edge genetic engineering technology to build upon this important discovery to determine precisely how mutations in DIS3L2 promote Wilms tumor growth. We will also exploit our new knowledge to test a novel targeted therapeutic strategy for Wilms tumors in mouse models. Successful completion of these experiments will lead to a new understanding of the causes of Wilms tumor, and will lead directly to new strategies for improved treatment of this disease

- Kopp F, Mendell JT. “Functional Classification and Experimental Dissection of Long Noncoding RNAs.” Cell. (2018) Jan 25;172(3):393-407. doi: 10.1016/j.cell.2018.01.011. Review. PubMed PMID: 29373828

RP170207
BBB-penetrating redox-responsive smart drugs and exploiting the MGMT-driven S-phase checkpoint for chemotherapy of childhood brain cancers
Individual Investigator Research Awards for Cancer in Children and Adolescents
Kalkunte Srivenugopal, Ph.D.
Texas Tech University Health Sciences Center

Each year, about 4,300 children are diagnosed with brain tumors in the United States. Childhood brain cancers are deadly and rank as number two killer among pediatric patients. The last 20 years have seen some marked improvements in the survival of patients with mild medulloblastomas, however, the outlook for malignant gliomas, high-risk medulloblastomas, and diffuse brainstem gliomas in children has changed very little. Every brain tumor patient goes through chemotherapy using alkylating agents. However, the treatment fails because, these tumors have multiple genetic abnormalities, and malignant cells can escape the cytotoxic effects of drugs and develop resistance. Chemo-drugs for brain cancers are few and have changed little. There is a need for new and effective drugs; those that hit multiple targets simultaneously will be useful. There is also a DNA repair protein called MGMT, which removes the DNA damage is present at higher levels in pediatric brain tumors, and this reduces tumor cell killing. We are a bioorganic chemistry laboratory and have synthesized a small molecule called KSS-72, which gets into the brain, acts through increasing the oxidative stress, affects multiple targets and kills glioblastoma cells in cultures and in animals. We will engineer KSS-72 to selectively deliver DNA damaging agents to brain cancers. Further, the MGMT repair protein has been found to have non-repair functions in the DNA replication process. Inhibition of the MGMT activity with O6-benzylguanine reduced the extent of DNA synthesis. This finding provides us a new strategy of combining the MGMT inhibitors with DNA synthesis curtailing drugs to achieve brain tumor regression. We will synthesize brain penetrating S-phase specific drugs and test all compounds in cell culture and brain cancer animal models. Our efforts represent a major step forward in pediatric brain tumor management and encourage new clinical trials.

- Mostofa A, Punganuru SR, Madala HR, Srivenugopal KS. S-phase Specific Downregulation of Human O6-Methylguanine DNA Methyltransferase (MGMT) and its Serendipitous Interactions with PCNA and p21cip1 Proteins in Glioma Cells. Neoplasia. 2018 Apr;20(4):305-323. doi: 10.1016/j.neo.2018.01.010. Epub 2018 Mar 3. PubMed PMID: 29510343; PubMed Central PMCID: PMC5909491.

- Madala HR, Punganuru SR, Arutla V, Misra S, Thomas TJ, Srivenugopal KS. Beyond Brooding on Oncometabolic Havoc in IDH-Mutant Gliomas and AML: Current and Future Therapeutic Strategies. Cancers (Basel). 2018 Feb 11;10(2). pii: E49. doi: 10.3390/cancers10020049. Review. PubMed PMID: 29439493; PubMed Central PMCID: PMC5836081.

- Madala HR, Punganuru SR, Ali-Osman F, Zhang R, Srivenugopal KS. Brain- and brain tumor-penetrating disulfiram nanoparticles: Sequence of cytotoxic events and efficacy in human glioma cell lines and intracranial xenografts. Oncotarget. 2017 Dec 15;9(3):3459-3482. doi: 10.18632/oncotarget.23320. eCollection 2018 Jan 9. PubMed PMID: 29423059; PubMed Central PMCID: PMC5790476.

- Punganuru SR, Madala HR, Mikelis CM, Dixit A, Arutla V, Srivenugopal KS. Conception, synthesis, and characterization of a rofecoxib-combretastatin hybrid drug with potent cyclooxygenase-2 (COX-2) inhibiting and microtubule disrupting activities in colon cancer cell culture and xenograft models. Oncotarget. 2018 May 25;9(40):26109-26129. doi: 10.18632/oncotarget.25450. eCollection 2018 May 25. PubMed PMID: 29899846; PubMed Central PMCID: PMC5995258.

RP160844
Center for Innovative Drug Discovery: Enhancement of a Shared Cancer Resource for South Texas
Core Facilities Support Awards
Stanton McHardy, Ph.D.
The University of Texas at San Antonio

This proposal outlines the enhancement and growth of the existing Center for Innovative Drug Discovery (CIDD), a truly first of its kind resource of core facilities and capabilities in South Texas to better support the discovery and development of new cancer therapeutics. The CIDD, which is comprised of two integrated core facilities for Medicinal Chemistry at UTSA and High Throughput Screening at UTHSCSA, has been providing researchers in San Antonio and South Texas access to coordinated technologies, services and expertise that advance drug discovery and development. The CIDD core facilities provide pharmaceutical industry level resources, capabilities and expertise to build collaborative programs with both academic and private industry researchers working on truly novel cancer pathways and mechanisms, thus supporting the translation of basic scientific discoveries into tangible pre-clinical candidates for further developed into novel therapies or diagnostics. The CIDD is working to fill a substantial unmet need for cancer research support in San Antonio and South Texas by providing a collaborative research platform to advance truly novel cancer ideas into tangible targeted therapies for a wide variety of cancer types. The long-term goal of our proposal is to expand our Center's capabilities in high throughput screening at UTHSCSA and in medicinal chemistry at UTSA to synergistically develop the next generation of chemotherapies and advance cancer research for all types of cancer.

- Dybdal-Hargreaves NF, Risinger AL, Mooberry SL. "Regulation of E-cadherin localization by microtubule targeting agents: rapid promotion of cortical E-cadherin through p130Cas/Src inhibition by eribulin". Oncotarget. 2017 Dec 31;9(5):5545-5561. doi: 10.18632/oncotarget.23798. eCollection 2018 Jan 19. PubMed PMID: 29464017

- De La Chapa J, Singha PK, Sallaway M, Self K, Nasreldin R, Dasari R, Hart M, Kornienko A, Just J, Smith JA, Bissember AC, Gonzales CB. Novel polygodial analogs P3 and P27:

"Efficacious therapeutic agents disrupting mitochondrial function in oral squamous cell carcinoma". Int J Oncol. (2018) Dec;53(6):2627-2636. doi: 10.3892/ijo.2018.4585. Epub 2018 Oct 5. PubMed PMID: 30320372

RP170691
Patient-derived Xenograft and Advanced In Vivo Models (PDX-AIM) Core Facility
Core Facilities Support Awards
Michael Lewis, Ph.D.
Baylor College of Medicine

With a few exceptions, traditional cancer research using tumor-derived cell lines grown on plastic have failed to yield results that benefit cancer patients. There are many reasons for this failure. To circumvent these shortcomings, researchers have begun to use "patient-derived xenografts" (PDX), and other models in which human tumors are grown in living hosts, including the mouse and the fertilized chicken egg. Development of a Patient-Derived Xenograft and Advanced In Vivo Models (PDX-AIM) Core is a high priority for Baylor College of Medicine (BCM) and its affiliate, The Texas Children's Hospital (TCH). BCM established a new PDX-AIM Core in 2016 jointly backed by the BCM Advanced Technology Laboratories and the Dan L. Duncan Cancer Center. The Core currently provides PDX development, and limited experimental assistance to two of the five existing PDX Programs. Our goal is to unify existing PDX programs, to develop at least six new PDX programs, specifically rare pediatric and adult tumors, and to provide infrastructure to expand services greatly Using two experimental platforms (mouse and egg), the overarching goal of the PDX-AIM Core is to provide computational and experimental infrastructure, as well as technical expertise to generate, characterize, manage, and experiment with, large collections of state-of-the-art in vivo cancer models for multiple organ sites that retain biological fidelity with the tumor of origin. By necessity, the core will be structured as a "decentralized" facility based on expertise for each cancer type. Core services will be provided on a subsidized chargeback basis, as per the capabilities of organ-specific PDX Programs. New PDX Program initiatives will be supported by a competitive pilot project program. This proposed Core directly addresses five CPRIT research program priorities. Thus, we anticipate this PDX-AIM Core to have a significant impact on cancer research at BCM/TCH, Texas, and indeed world-wide.

- Zhao N, Cao J, Xu L, Tang Q, Dobrolecki LE, Lv X, Talukdar M, Lu Y, Wang X, Hu DZ, Shi Q, Xiang Y, Wang Y, Liu X, Bu W, Jiang Y, Li M, Gong Y, Sun Z, Ying H, Yuan B, Lin X, Feng XH, Hartig SM, Li F, Shen H, Chen Y, Han L, Zeng Q, Patterson JB, Kaipparettu BA, Putluri N, Sicheri F, Rosen JM, Lewis MT, Chen X. Pharmacological targeting of MYC-regulated IRE1/XBP1 pathway suppresses MYC-driven breast cancer. J Clin Invest. 2018 Apr 2;128(4):1283-1299. doi: 10.1172/JCI95873. Epub 2018 Feb 26. PubMed PMID: 29480818; PubMed Central PMCID: PMC5873887.

RP170719
GCC Center for Advanced Microscopy and Image Informatics
Core Facilities Support Awards
Michael Mancini, Ph.D.
Texas A&M University System Health Science Center

Researchers from Gulf Coast Consortium (1) institutions have established a new, highly collaborative research core facility, the Center for Advanced Microscopy and Image Informatics (CAMII), to provide the GCC's cancer researchers with access to sophisticated imaging and computational resources that will enable them to address critical questions in both basic and translational cancer research. The program includes projects addressing fundamental questions in cancer biology as well as projects whose goal is the development of new therapies for the prevention and treatment of cancer. CAMII's advanced imaging technologies will be used by established investigators and junior investigators to conduct studies that are targeted to the development of new therapies for many different types of cancer.

CAMII has three specific goals: Goal 1: to provide critical support to outstanding basic and translational cancer research projects; Goal 2: to contribute to the development of new imaging and informatics technologies for cancer research; Goal 3: to provide training on the application of advanced imaging technologies to critical problems in cancer research. By promoting highly collaborative and productive partnerships between experts in advanced imaging research and outstanding cancer researchers, CAMII will support CPRIT's goal of promoting innovation in cancer research and accelerating the development of breakthroughs in the search for new ways to prevent and/or to treat cancer.

- Parikh N, Shuck RL, Gagea M, Shen L, Donehower LA. Enhanced inflammation and attenuated tumor suppressor pathways are associated with oncogene-induced lung tumors in aged mice. Aging Cell. 2018 Feb;17(1). doi: 10.1111/acel.12691. Epub 2017 Oct 18. PubMed PMID: 29047229; PubMed Central PMCID: PMC5771401.

- Padmanabhan A, Candelaria N, Wong KK, Nikolai BC, Lonard DM, O'Malley BW, Richards JS. USP15-dependent lysosomal pathway controls p53-R175H turnover in ovarian cancer cells. Nat Commun. 2018 Mar 28;9(1):1270. doi: 10.1038/s41467-018-03599-w. PubMed PMID: 29593334; PubMed Central PMCID: PMC5871815.

- Yu W, Chen Y, Dubrulle J, Stossi F, Putluri V, Sreekumar A, Putluri N, Baluya D, Lai SY, Sandulache VC. Cisplatin generates oxidative stress which is accompanied by rapid shifts in central carbon metabolism. Sci Rep. 2018 Mar 9;8(1):4306. doi: 10.1038/s41598-018-22640-y. PubMed PMID: 29523854; PubMed Central PMCID: PMC5844883.

- Nair A, Chung HC, Sun T, Tyagi S, Dobrolecki LE, Dominguez-Vidana R, Kurley SJ, Orellana M, Renwick A, Henke DM, Katsonis P, Schmitt E, Chan DW, Li H, Mao S, Petrovic I, Creighton CJ, Gutierrez C, Dubrulle J, Stossi F, Tyner JW, Lichtarge O, Lin CY, Zhang B, Scott KL, Hilsenbeck SG, Sun J, Yu X, Osborne CK, Schiff R, Christensen JG, Shields DJ, Rimawi MF, Ellis MJ, Shaw CA, Lewis MT, Westbrook TF. Combinatorial inhibition of PTPN12-regulated receptors leads to a broadly effective therapeutic strategy in triple-negative breast cancer. Nat Med. 2018 May;24(4):505-511. doi: 10.1038/nm.4507. Epub 2018 Mar 26. PubMed PMID: 29578538.

- Samaha H, Pignata A, Fousek K, Ren J, Lam FW, Stossi F, Dubrulle J, Salsman VS, Krishnan S, Hong SH, Baker ML, Shree A, Gad AZ, Shum T, Fukumura D, Byrd TT, Mukherjee M, Marrelli SP, Orange JS, Joseph SK, Sorensen PH, Taylor MD, Hegde M, Mamonkin M, Jain RK, El-Naggar S, Ahmed N. A homing system targets therapeutic T cells to brain cancer. Nature. 2018 Sep;561(7723):331-337. doi: 10.1038/s41586-018-0499-y. Epub 2018 Sep 5. PubMed PMID: 30185905.

- Brunetti L, Gundry MC, Sorcini D, Guzman AG, Huang YH, Ramabadran R, Gionfriddo I, Mezzasoma F, Milano F, Nabet B, Buckley DL, Kornblau SM, Lin CY, Sportoletti P, Martelli MP, Falini B, Goodell MA. Mutant NPM1 Maintains the Leukemic State through HOX Expression. Cancer Cell. 2018 Sep 10;34(3):499-512.e9. doi: 10.1016/j.ccell.2018.08.005. PubMed PMID: 30205049; PubMed Central PMCID: PMC6159911.

- Szwarc MM, Kommagani R, Putluri V, Dubrulle J, Stossi F, Mancini MA, Coarfa C, Lanz RB, Putluri N, DeMayo FJ, Lydon JP, O'Malley BW. Steroid Receptor Coactivator-2 Controls the Pentose Phosphate Pathway through RPIA in Human Endometrial Cancer Cells. Sci Rep. 2018 Sep 3;8(1):13134. doi: 10.1038/s41598-018-31372-y. PubMed PMID: 30177747; PubMed Central PMCID: PMC6120906.

PP180012
Vaccinating medically underserved women against HPV

Evidence-Based Cancer Prevention Services
Abbey Berenson, M.D.
The University of Texas Medical Branch at Galveston

In spite of its ability to prevent cancer and strong recommendations for vaccination from the Centers for Disease Control and Prevention, the HPV vaccine remains underutilized in the US. Only 65 percent of girls 13-17 years old have initiated the vaccine series and completion rates are even lower. Among 19–26-year old's, only 42 percent of women have initiated the vaccine series. Vaccination rates are much lower among women receiving care at the University of Texas Medical Branch's gynecology clinics in McAllen and Galveston, Texas (Hidalgo and Galveston Counties). A medical records review indicates that an average of only 18 percent of eligible young women attending these clinics have received even 1 dose of the vaccine. This is concerning given that many patients attending these clinics are low-income or members of racial/ethnic groups with higher rates of HPV-related cancer incidence and mortality. Additionally, a significant number reside in medically underserved areas. Thus, patients attending these clinics would greatly benefit from a CPRIT-funded program that reduced barriers and helped young women easily obtain this highly effective vaccine.

- Hirth JM, Batuuka DN, Gross TT, Cofie L, Berenson AB. Human papillomavirus vaccine motivators and barriers among community college students: Considerations for development of a successful vaccination program. Vaccine. 2018 Feb 14;36(8):1032-1037. doi: 10.1016/j.vaccine.2018.01.037. PubMed PMID: 29366708; PubMed Central PMCID: PMC5801161.

Active Clinical Trials/Clinical Studies

RP150006
Defining and Treating Targetable Lesions in AYA Acute Lymphoblastic Leukemia
Individual Investigator Research Awards for Cancer in Children and Adolescents
Marina Konopleva, M.D.
The University of Texas M. D. Anderson Cancer Center

Acute lymphoblastic leukemia (ALL) is the most common form of cancer in children. Despite tremendous improvements in the outcomes, a subset of children relapses and often succumbs to their disease. In adults, the outcomes remain vastly inferior, and most patients are expected to die either of their disease or of treatment-related toxicities. The need for novel therapies is thus unquestioned. A major recent advance in understanding the biology of ALL was the discovery of a novel category of "Ph-like" ALL which exhibit gene expression signatures similar to patients with "Philadelphia (Ph)" chromosome but are lacking Ph-chromosome. Further discoveries have demonstrated that the tumors in these patients with ALL are driven by alterations in oncogenic kinases amenable to therapy with FDA-approved tyrosine kinase inhibitors (TKIs). Depending on the underpinning genetics, these patients may respond to ABL/PDGFR inhibitor dasatinib, which has recently improved survival in Ph(+) ALL; or JAK2 inhibitor ruxolitinib, approved for therapy of JAK2-driven myeloproliferative neoplasms. This concept, developed in pre-clinical leukemia models, was validated in reports of the success of TKIs in refractory EBF1-PDGFRB Ph-like ALL patients. Recent studies with our collaborator from St. Jude's Charles Mullighan have shown that the frequency of "Ph-like" ALL increases with age, whereby one-third of young adults with ALL have actionable genetic lesions and very poor outcomes. In this study, we will (1) design and validate the genetic platform that can rapidly identify high-risk Ph-like ALL patients; (2) treat relapsed or refractory Ph-like ALL patients with TKI matched against patients' specific genetic make-up, alone or in combination with salvage chemotherapy in a clinical trial setting; and (3) perform deep RNA sequencing and proteomic analyses to characterize novel actionable targets. We will test novel therapies in immunodeficient mice engrafted with human leukemia samples.

- NCT02420717 Ruxolitinib or Dasatinib With Chemotherapy in Patients With Philadelphia Chromosome (Ph)-Like Acute Lymphoblastic Leukemia (ALL).
    - Phase I/Phase II
    - 80 projected total patients expected for accrual: 80

RP170722
Identification of critical dependencies and actionable therapeutic options in Smarcb1-deficient pediatric tumors
High-Impact/High-Risk Research Awards
Giulio Draetta, M.D.
The University of Texas M.D. Anderson Cancer Center

Cells have special enzymes that control how genes are expressed. Because of this, even when two people may share the same genes, these enzymes can impact how those genes are expressed and influence physiological processes. Increasingly, we are understanding that these enzymes controlling gene expression may significantly impact the development and progression of cancer. The function of one of these enzymes, Smarcb1, has been documented to be lost in a group of very aggressive pediatric tumors, malignant rhabdoid tumors (MRTs) and renal medullary carcinomas (RMCs). Although very rare, patients with these tumors suffer an overall dismal prognosis, especially very young patients under one year of age. It has proven very challenging to study the biology MRTs and RMCs for a number of reasons. For one, the tumors are very rare, making tumor specimens very difficult to obtain. Other approaches to model the disease are difficult because the deletion of SMARCB1 causes myriad negative effects on cells and tissues that are not directly related to the reasons SMARCB1 deficiency causes cancer. To address these problems, we have established collaborations with The Departments of Genitourinary Oncology at the MD Anderson Cancer Center and Memorial Sloan Kettering Cancer Center to obtain these rare tissue samples, and we have developed a novel mouse model of the disease that will allow us to study Smarcb1-deficient tumors. We will employ these models to screen for unknown dependencies within these tumors that may lend themselves to therapeutic intervention, including potentially the use of drugs that are currently available for patients with cancer, but that are not yet proven to be effective for these pediatric indications. If successful, our research may illuminate novel approaches to treat the young patients who present with these devastating diagnoses.

- NCT03587662 Trial of Ixazomib Combined With Gemcitabine and Doxorubicin in Patients With Renal Medullary Carcinoma.
    - Phase II
    - Projected total patients expected for accrual: 30

Clinical Trial Related Press Release 2/11/2019

New therapeutic target found for aggressive pediatric cancers with few treatment options

Preclinical study identifies vulnerability in orphan cancers with SMARCB1 mutations, spurs launch of Phase II clinical trial

UT MD Anderson Cancer Center

Researchers at The University of Texas MD Anderson Cancer Center have discovered that malignant rhabdoid tumors (MRT), a rare pediatric cancer without effective treatments, may be sensitive to drugs that block the cancer cell's ability to dispose of misfolded proteins.

https://www.eurekalert.org/pub_releases/2019-02/uotm-ntt021119.php

DP160014
Salarius Pharmaceuticals - Developing epigenetic drugs that treat Rare Pediatric Cancers
New Company Product Development Awards
David Arthur, MBA
Salarius Pharmaceuticals LLC

Salarius specializes in developing novel drugs for rare pediatric cancers and other cancers by focusing on treatments that interrupt the final steps of the signaling cascade. Our first drug, SP-2577, targets the Lysine Specific Histone Demethylase 1 pathway (LSD1), a cellular control protein that's overactive in a range of cancers. Here Salarius has developed a first in class highly specific LSD1 inhibitor that we will test in Ewing's Sarcoma and other undifferentiated sarcomas, in addition to late stage prostate cancer. We plan to file an IND in early 2016 and initiate phase 1 clinical studies in Ewing's and prostate cancer in June 2016. Ewing's is a rare devastating pediatric, adolescent and young adult bone cancer with no approved treatment. Roughly 50% of Ewing's patients fail to respond to chemotherapy, radiation and surgical treatment and face 70%-80% mortality. If successful, a treatment for Ewing's Sarcoma represents hope for thousands of patients and their families where current treatments are often woefully inadequate. Successful phase 1/2 studies could support an accelerated regulatory process with a Ewing's orphan drug indication approved by Q3'19. Salarius plans to relocate to Texas and set up a collaborative research effort to discover new drugs in its quest to become an integrated pharmaceutical company. Our business model is based on tight integration with academia and creating win-win environments between Salarius and academic cancer centers.

- NCT03600649 Clinical Trial of SP-2577 (Seclidemstat) in Patients With Relapsed or Refractory Ewing Sarcoma. Salarius Pharmaceuticals, LLC
    - Phase I

RP150164
Using imaging and computational tools to improve risk stratification in children with bone cancer
Individual Investigator Research Awards for Cancer in Children and Adolescents
Patrick Leavey, M.D.
The University of Texas Southwestern Medical Center

Osteosarcoma is the most common bone cancer in children and young adults but at least 40% of patients die of this disease. There is an urgency and critical need to identify accurately and as early as possible those patients at high risk of dying. Basic features of tumor spread and if the tumor is surgically removable identify such patients, while poor tumor response to 10 weeks of chemotherapy is another high-risk feature. Unfortunately identifying these features has not yet allowed effective change in therapy to improve patient survival. Yet, since tumor response in other childhood cancers allows effective tailoring of therapy, we believe that the inability to achieve improvements for patients with osteosarcoma may be the result of a semi-quantitative process to evaluate response that is available too late to make any meaningful change. However modern technologies address these two fundamental problems. Whole slide imaging allows virtual pathology evaluation of an entire tumor sample and computer-based systems can be developed to automate the identification of subtle changes in a tumor representing features of response. Also computer software can merge pathology images with images from non-invasive radiology techniques such as magnetic resonance imaging (MRI). The benefits of this include firstly more precise identification of subtle changes by MRI and secondly, and more importantly, earlier identification of these predictive changes than is possible currently. We predict that early identification of MRI features will correlate closely with pathological features of responding tumors and that this will transform a clinical practice that has been unchanged for decades. Accurate and early identification of tumor characteristics that predict high-risk will allow greater specificity in biopsies, allow greater confidence in predicting patients at highest-risk and potentially allow tailored therapy to the needs of individual patient with osteosarcoma.

- Prospective evaluation of the use of imaging and computational tools to improve risk stratification in children with bone cancer.
    - Phase: Pilot
    - Projected total patients expected for accrual: 24

- Using Imaging and Computational Tools to Improve Risk Stratification in Children with Bone Cancer.
    - Phase: Pilot
    - Projected total patients expected for accrual: 50

RP150416
Translational Investigations On Fenretinide and Safingol For Pediatric Cancer Use
Individual Investigator Research Awards for Cancer in Children and Adolescents
Barry Maurer, M.D.
Texas Tech University Health Sciences Center

We are developing a new kind of chemotherapy to fight pediatric cancers resistant to current therapies. This new chemotherapy uses high doses of a drug, called fenretinide, to increase certain toxic waxes, called dihydroceramides, in cancer cells and kill them. Because these waxes do not increase in normal cells, fenretinide is well-tolerated clinically. Using new formulations of fenretinide, we have been able to reduce, even eliminate, pediatric neuroblastoma cancer cells in some children in early clinical trials. We will now try to further increase the killing power of fenretinide by combining it with an artificial wax, called safingol. In the laboratory, when fenretinide-induced waxes meet safingol in cancer cells, the killing power can increase up to ten-fold. Interestingly, we have determined that feeding cancer cells certain fats at the same time that fenretinide is given causes certain of the toxic waxes to increase even further. This may be clinically useful because some of the waxes are better at killing cancer cells than others. We have also discovered that cancer cells try to protect themselves from fenretinide by revving up a protective process in the cell, called autophagy. We have early evidence that inhibiting autophagy allows the toxic waxes to kill the cancer cells faster and better. In this project, we will make a clinical drug supply of fenretinide and safingol to test in children with relapsed cancers. We will determine which specific fats are the best to combine with fenretinide to increase the toxic waxes in neuroblastoma cancer cells. We will also determine the best ways to go about inhibiting autophagy in neuroblastoma cells for use in a future clinic trial with fenretinide. Lastly, we will try to determine if there are autophagy-related chemicals in cancer cells that may allow us to predict which neuroblastoma cancers are more apt to respond to fenretinide so we better know which patients to treat.

- Phase I trial of Intravenous Fenretinide and Intravenous Safingol in Pediatric Relapsed Malignancies. Texas Tech University Health Sciences Center
    - Phase I
    - Projected total patients expected for accrual: 24

RP170493
For Our Children: A tailored multi-level intervention for parents and healthcare providers to increase HPV vaccination rates
Individual Investigator Research Awards for Prevention and Early Detection
Maria Fernandez, Ph.D.
The University of Texas Health Science Center at Houston

Infection with Human papillomavirus (HPV) causes a number of cancers including male and female genital cancers, anal cancer and cancers of the throat. Being vaccinated for HPV can reduce infection with HPV and death from HPV-associated cancers, but vaccination rates among fall below the Healthy People 2020 goal of 80% completion. National data for Hispanic adolescents (aged 13-17) suggest 66.3% of females and 54.2% of males have initiated the 3-dose vaccine and only 49.6% of females and 27.8% of males completed the vaccine. Both parental and provider knowledge, beliefs, and behaviors impact adolescent HPV vaccination. Parents often have low knowledge about HPV and the vaccine, do not believe their child is at risk, have safety concerns and often do not receive a provider recommendation. Providers often fail to give a strong recommendation and wait until adolescents are older to recommend the vaccine. The goal of the proposed study is to improve HPV vaccination rates among Hispanic adolescents (aged 11-17). In Aim 1, we will test a tailored interactive multimedia intervention (originally developed for parents of Hispanic girls) that was adapted for parents of Hispanic boys to determine its effectiveness at increasing HPV vaccination uptake for Hispanic boys. We will also test an intervention using parental text message reminders to increase HPV vaccination in Hispanic adolescents. In Aim 2, we will enhance an existing tailored interactive multimedia intervention for parents by developing a training component for healthcare providers to increase provider recommendation for the HPV vaccine using an approach called Intervention Mapping. In Aim 3, we will conduct a study with three conditions (provider training alone, provider training with the parent intervention, and usual care) to determine the effectiveness and cost-effectiveness of each condition on increasing HPV vaccine initiation and completion among Hispanic adolescents

- For Our Children: A Tailored multi-level intervention for parents and healthcare providers to increase HPV vaccination rates. The University of Texas Health Science Center at Houston
    - Phase: Feasibility
    - Projected total patients expected for accrual: 1050

DP160057
Clinical Evaluation of a Novel T Cell Therapy (BPX-501) for the Treatment of Children and Adults with AML
Texas Company Product Development Awards
Joseph Woodard, M.D.
Bellicum Pharmaceuticals, Inc.

Many patients with leukemia are cured by a stem cell transplant after intense chemotherapy. However, cancer relapse, infection, and graft versus host (GvHD) are common in the months after a transplant. The problem is that harmful T cells in the transplant cannot be separated from essential, helpful T cells that kill residual cancer and help stem cells become established. Harmful T cells attack the skin, intestines, and the liver, which they see as foreign. For these reasons, many cancer patients without a matched donor cannot receive a transplant, and those that do risk severe, often fatal complications. Bellicum Pharmaceuticals has developed a revolutionary new T-cell therapy (BPX-501) to solve the critical problems associated with non-matched transplants. Bellicum inserts a "safety switch" into donor T-cells, which allows the physician to kill harmful T cells while preserving those helpful T-cells that protect from infection, assist the new stem cells, and kill residual cancer. This project will test a new combination therapy consisting of BPX-501 along with donor stem cells that have been specially prepared to maintain certain beneficial cells that can work together with BPX-501. Bellicum will treat adults and children with a very serious form of leukemia called AML, who have failed conventional therapy and have little chance for cure. The results of this trial could revolutionize cancer treatment and provide hope to many patients with no current alternatives.

- A Randomized Phase II/III Study of αβ T-Cell-Depleted, Related, Haploidentical Hematopoietic Stem Cell Transplant (Haplo-HSCT) Plus BPX-501 T-Cell Infusion vs Haplo-HSCT Plus Post Transplant Cyclophosphamide (Post-Cy) in Adults with Acute Myeloid Leukemia (AML) or Myelodysplastic Syndrome (MDS). Bellicum Pharmaceuticals, Inc.
    - Phase II, Phase III
    - Projected total patients expected for accrual:190

BIOGRAPHICAL SKETCH

NAME: Skapek, Stephen X.

eRA COMMONS USER NAME (credential, e.g., agency login): SSKAPEK

POSITION TITLE: Professor

EDUCATION/TRAINING

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
Duke University, Durham, NC	B.A.	1984	Chemistry, Latin
Duke University School of Medicine, Durham, NC	M.D.	1988	Medicine
Intern and Resident in Pediatrics, Wilford Hall USAF Medical Center, San Antonio, TX		1988-1991	Pediatrics
Fellow in Hematology/Oncology, Dana Farber Cancer Institute and Children's Hosp., Boston, MA		1991-1994	Hematology/Oncology
Research Fellow in Pediatrics, Harvard Medical School, Boston, MA		1992-1995	Dev/Mol Biology

A. Personal Statement

Although I was trained as a clinician, my academic work has largely focused on applying molecular and cell biology tools with cell-based and mouse models to carry out laboratory research addressing, among other things, how cell cycle control is orchestrated with differentiation in skeletal myoblasts and how the differentiation program is derailed in rhabdomyosarcoma. As a physician-scientist, I have maintained a close relationship with the Children's Oncology Group (COG), in which capacity I now serve as vice-Chair over Biology on the Soft Tissue Sarcoma Committee and as a member of the COG Executive Committee and Scientific Council, as well as co-PI of a U10 grant from the NCI to support the COG Solid Malignancies Integrated Translational Science Center. As such, I am almost uniquely positioned to conduct rhabdomyosarcoma studies at the interface between the laboratory and the clinic, especially as we begin to translate findings related to rhabdomyosarcoma biology back to the clinic. During my 25 year career, I have successfully mentored 11 Postdoctoral Fellows, 6 graduate students, and other young scientists, some of whom have gone on to hold stellar research careers of their own at some of the top institutions in the country.

B. Positions and Honors

1994-1995 Assistant in Medicine, Division of Hematology/Oncology, Children's Hospital, Boston, MA
Instructor in Pediatrics, Department of Pediatrics, Harvard Medical School, Boston, MA

1995-1996 Staff Physician, Division of Hematology/Oncology, Department of Pediatrics, Wilford Hall Medical Center, San Antonio, TX

1995-1997 Research Scientist (non-salary), Institute of Biotechnology, University of Texas Health Science Center, San Antonio, TX (Mentor: Eva Lee, Ph.D.)

1996-1999 Assistant Professor of Pediatrics, Uniformed Services University of Health Sci., Bethesda, MD

1996-1999 Chief of Pediatric Oncology, Division of Hematology/Oncology, Department of Pediatrics, Wilford Hall Medical Center, San Antonio, TX

1997-1999 Assistant Professor (non-tenure, research) (non-salary), Institute of Biotechnology, University of Texas Health Science Center, San Antonio, TX
1999-2005 Assistant Member, Department of Hematology/Oncology, St. Jude Children's Research Hospital, Memphis, TN
2003-2006 Assistant Professor, Department of Ophthalmology, University of Tennessee Health Science Center College of Medicine, Memphis, TN
2005-2007 Associate Member, Department of Hematology/Oncology, St. Jude Children's Research Hospital, Memphis, TN
2006-2007 Associate Professor of Pediatrics, University of Tennessee Health Science Center College of Medicine, Memphis, TN
2007-2011 Associate Professor, Department of Pediatrics, Division of Hematology/Oncology, University of Chicago
2011-present Professor (with Tenure) and Director, Division of Hematology/Oncology, Department of Pediatrics, UT Southwestern Medical Center, Dallas, TX
2011-present Medical Director, Gill Center for Cancer and Blood Disorders, Children's Medical Center, Dallas, TX

AWARDS/HONORS

1983 Phi Beta Kappa, Duke University
1984 Summa Cum Laude graduate, Duke University
1988 Alpha Omega Alpha, Duke University
1992 United States Air Force Achievement Medal
1993 NIH Clinical Investigator Development Award (K08)
1994 G and P Foundation for Cancer Research Medical Research Award
2004 American Cancer Society Research Scholar
2011 Children's Cancer Fund Distinguished Professorship in Pediatric Oncology Research
2013 UT Southwestern Distinguished Chair in Pediatric Oncology Research

C. Contributions to Science (selected from 78 publications)

Discovery of the molecular mechanism for coupling myogenic differentiation to cell cycle arrest in developing skeletal muscle.

As a postdoctoral fellow with Andrew Lassar at Harvard Medical School, I made the discovery that the Cyclin D1 cell cycle regulatory protein, but not other G1-phase cell cyclins, blunts the capacity for the MyoD protein to drive the expression of muscle specific promoters. Importantly, Cyclin D1 activity falls during this developmental process, and a key Cyclin-dependent kinase inhibitor, p21, gets induced. Moreover, Cyclin D1 seems to block muscle gene expression independently of the retinoblastoma protein, R. This work was published in two manuscripts: Skapek et al., Science 267:1022-1024, 1995; and Skapek et al, Mol Cell Biol 16:7043-7053, 1996. To this day, this Cyclin D/Cdk/RB axis is still felt to play a pivotal role orchestrating cell proliferation arrest and the first steps in muscle differentiation. Work to define regulatory mechanisms of the initial steps in myogenesis continues to this day: Wilson RA, Liu J, Xu L, Annis J, Helmig S, Moore G, Timmerman C, Grandori C, Zheng Y, and Skapek SX. Scientific Reports. 2016 Feb 5;6:20376. Doi:10.1038/srep20376. Elements of on-going work focused on the iExCN-analysis pipeline are offering new insights into possible regulators of this differentiation blockade.

Discovery that the Arf tumor suppressor gene is required to block primary vitreous hyperplasia in the developing mouse eye.

In my first independent faculty position at the St. Jude Children's Research Hospital, while attempting to generate a mouse model for retinoblastoma, I discovered that the Arf tumor suppressor gene was essential for normal eye development. This work provided the first, and still the best understood, p53-independent role for Arf; provided a potential molecular mechanism for the human eye disease, Persistent Hyperplastic Primary Vitreous; and presents the only clear developmental role for the Arf tumor suppressor gene. This chance observation has led to close to 15 years of successive R01 funding in my laboratory. The first author on the paper reporting this finding (McKeller RN, et al. Proceedings of the National Academy of Science 99: 3848-3853, 2002) was a research technician in my laboratory, who subsequently pursued graduate training in pharmacy; and I have published 14 additional manuscripts defining a new genetic and biochemical pathway stemming from TGF beta to PDGFR beta through the Arf tumor suppressor gene.

Discovery that PAX-FOXO1 expression correlates with outcome in children with rhabdomyosarcoma
In my role as vice chair of the COG Soft Tissue Sarcoma Committee, I led a team to demonstrate that expression of the PAX3 (or PAX7)-FOXO1 fusion gene is a robust biomarker that predicts survival in children with rhabdomyosarcoma (Skapek SX, Anderson J, Barr FG, Bridge JA, Gastier-Foster JM, Parham DM, Rudzinski ER, Triche T, Hawkins DS. PAX-FOXO1 fusion status drives unfavorable outcome for children with rhabdomyosarcoma: A Children's Oncology Group report. Pediatric Blood and Cancer 60: 1411-1417, 2013). This report was the first to demonstrate this fact by utilizing specimens prospectively collected in the context of a single clinical trial, and this finding has formed the basis for incorporating that biomarker as a clinical test for children with this disease. This work is a part of a growing body of clinical/translational research based on my role in the COG Soft Tissue Sarcoma committee, evidenced by 11 additional manuscripts on soft tissue sarcoma since 2015.

Demonstrating that measuring mRNA transcripts utilizing nCounter can serve as a molecular classifier for children with rhabdomyosarcoma.
In my role as vice chair of the COG Soft Tissue Sarcoma Committee, I co-led an NIH funded project to bring gene expression signatures into routine clinical practice. This work led to the development and validation of the nCounter platform to quantify mRNA in formalin-fixed paraffin-embedded rhabdomyosarcoma specimens. The first manuscript in that project represents a computational paper (Wilson RA, Teng L, Bachmeyer KM, Bissonette ML, Husain AN, Parham DM, Triche TJ, Wing MR, Gastier-Foster JM, Barr FG, Hawkins DS, Anderson JR, Skapek SX*, and Volchenboum SL*. A novel algorithm for simplification of complex gene classifiers in cancer. Cancer Research 73: 5625-5632, 2013), but this manuscript leverages data that we generated utilizing nCounter in the same types of specimens to be studied in the current proposal. This work led to a second manuscript in which nCounter use to measure the MG5 gene expression signature in rhabdomyosarcoma specimens correlates with clinical outcome (Hingorani P, Missiaglia E, Shipley J, Anderson JR, Triche TJ, Delorenzi M, Gastier-Foster J, M. Wing M, D.S. Hawkins DS, and Skapek SX. Clinical Cancer Research 21: 4733-4739, 2015). These types of manuscripts directly support my capacity to steer laboratory-based findings in the current proposal toward the clinic.

For a full list of publications, see: http://www.ncbi.nlm.nih.gov/pubmed/?term=skapek

D. Additional Information: Research Support and/or Scholastic Performance

Ongoing

R01EY019942-04 Skapek (PI) 04/01/14 – 03/31/18
NIH/NEI
Tgf β2 Controls p19Arf during Eye Development
The major goal of this research proposal is to uncover mechanisms by which Transforming growth factor β2 controls the expression of the *Arf* tumor suppressor during eye development.
Role: PI

RP120685 – Administrative Core Skapek (PI) 09/01/12 – 08/30/18
Cancer Prevention & Research Institute of Texas (CPRIT)
Molecularly Targeted Therapy for Soft Tissue Sarcoma in Texas
$233,740.41
The major goal is to provide administrative support to a multi-investigator research proposal in which genetics and functional genomics are utilized to identify the key vulnerabilities in soft tissue sarcoma in children.
Role: PI

RP120685 – Project 2 Skapek (PI) 09/01/12 – 08/30/18
Cancer Prevention & Research Institute of Texas (CPRIT)
High Throughput Screening for Sarcoma Cell Proliferation and Survival Factors
$581,336.79
The major goal is to carry out functional genomics studies cell proliferation/survival factors in soft tissue sarcomas that commonly occurs in children and young adults.

Role: PI

P30 CA142543 Willson (PI) 08/1/15 – 07/31/20
NIH/NCI
Cancer Center Support Grant
The goals of the CCSG are to strengthen and develop interdisciplinary, transdisciplinary and collaborative research focused on understanding the prevention, causes and treatment of human cancers.
Role: Scientific Program Leader

U10CA180884-04 Skapek/Adamson (MPI) 03/01/15 – 02/28/19
NIH (NCI)
COG NCTN Solid Malignancy Integrated Translational Science Center
Year 4 Direct Costs: $27,592.00
This grant provides funding to support (a) the infrastructure needed to coordinate translational research studies conducted as part of the Children's Oncology Group, and (b) provide funds to support translational research pilot studies developed through this Center. Dr. Skapek provides direct leadership of the Translational Science Center.
Role: PI/MPI

U10CA180886 Adamson (PI) 03/01/15 – 02/28/18
CHOP/ NIH (NCI)
Skapek - COG STS Biology Vice Chair
Direct Costs: $11,149.00
The grant provides funding to support the infrastructure needed for the Children's Oncology Group to conduct clinical research studies in children with cancer across North America and at several sites overseas. Salary support is provided to Dr. Skapek for his leadership roles in the Children's Oncology Group.
Role: Soft Tissue Sarcoma Committee vice-chair, D9902 Study Chair

U54CA196519 Clapp/Shannon (MPI) 09/01/15 – 08/30/20
Indiana University
Developmental and HyperActive RAS Tumor SPORE
Project 2: Targeted Therapies for Malignant Peripheral Nerve Sheath Tumor
The major goal of this project is to develop new therapeutic agents that previous laboratory studies reveal to be promising therapies for children with malignant peripheral nerve sheath tumor (MPNST), an aggressive soft tissue sarcoma commonly observed in patients with neurofibromatosis.
Role: Co-Leader Project 2

UTHSCSA Skapek (PI) 06/01/16 – 05/31/18
Texas Pediatric Patient Derived Xenograft Facility
Direct Costs: $450,657.00
Role: PI

Completed

RSG-040036-01-DDC (Skapek) 01/01/04–06/30/08
American Cancer Society
The Arf Tumor Suppressor as a Regulator of Vascular Regression
The major goals of this project are to determine how Arf alters expression of VEGF or other angiogenic factors to promote vascular regression in the eye and to determine how Arf expression alters tumor-induces angiogenesis.
Role: PI

Schering-Plough Research Institute (Skapek, site PI) 06/06/08 – 06/05/10
A Study to Determine the Activity of SCH 717454 in Subjects with Osteosarcoma or Ewing's Sarcoma That Has Relapsed After Standard Systemic Therapy
The goal of this clinical trial was to evaluate SCH 717454 in patients with Ewing and osteogenic sarcoma.

Role: Site PI

St. Baldrick's Foundation (Rudzinski) 07/01/10 – 06/30/11
Histologic criteria and surrogate markers alveolar Rhabdomyosarcoma
Immunohistochemical staining of rhabdomyosarcoma tissue samples will be performed in Dr. Skapek's laboratory for this project.
Role: PI of the subaward at The University of Chicago

RC2CA148216-02 (MPI: Triche/Skapek) 09/29/09 – 08/31/11
NIH/NCI
Translation of Predictive Cancer Biomarkers into Clinical Practice
The goal of this proposal is to create clinically useful diagnostic and prognostic biomarker profiles that can be applied to routinely processed (formalin fixed, paraffin embedded) tumor tissue and thus incorporated into the workup of every patient to be admitted on a COG STS RMS protocol.
Role: Co-PI

Desmoid Tumor Research Foundation (Skapek) 02/01/10 – 01/31/12
Deregulated mTOR in desmoid-type fibromatosis: Identification and validation of a new therapeutic target
The goal of this proposal is to directly test the hypotheses that (a) mTOR is active in desmoid tumor, (b) treatment with rapamycin can block mTOR activation, and (c) response to rapamycin will correlate with changes in desmoid tumor vascularity.
Role: PI

56745TX (Zheng) 09/1/12 – 12/31/14
Hyundai Hope on Wheels
Targeting the SRC oncogene to promote muscle differentiation as a new therapy for rhabdomyosarcoma
Major goal is to study how Src kinase affects normal muscle development and the biology of RMS cells, and test the effects of Src inhibition on RMS differentiation in preclinical models.
Role: Co – PI

R01EY0142368-80 (Skapek) 12/01/02 – 07/31/14
NIH/NEI
ARF Controls Vascular Regression during Eye Development
The major goal of this proposal is to understand molecular events preventing primary vitreous hyperplasia and guiding the regression of the hyaloid vascular system (HVS) during eye development Role: PI

Pediatric Cancer Research (Laetsch) 4/1/2015 – 3/31/2016
BEAR NECESSITIES FOUNDATION
Maximizing the Therapeutic Impact of CDK4/6 Inhibition in Rhabdomyosarcoma
The major goal of this project is to define optimal combination strategies for use of CDK4/6 inhibitors to treat rhabdomyosarcomas. Using in vitro and in vivo models, the ability of CDK4/6 inhibitors to synchronize the cell cycle and increase sensitivity to cytotoxic chemotherapy will be evaluated. Using similar models, the efficacy of the combination of CDK4/6 inhibition with MEK inhibition will also be evaluated.
Role: Collaborator

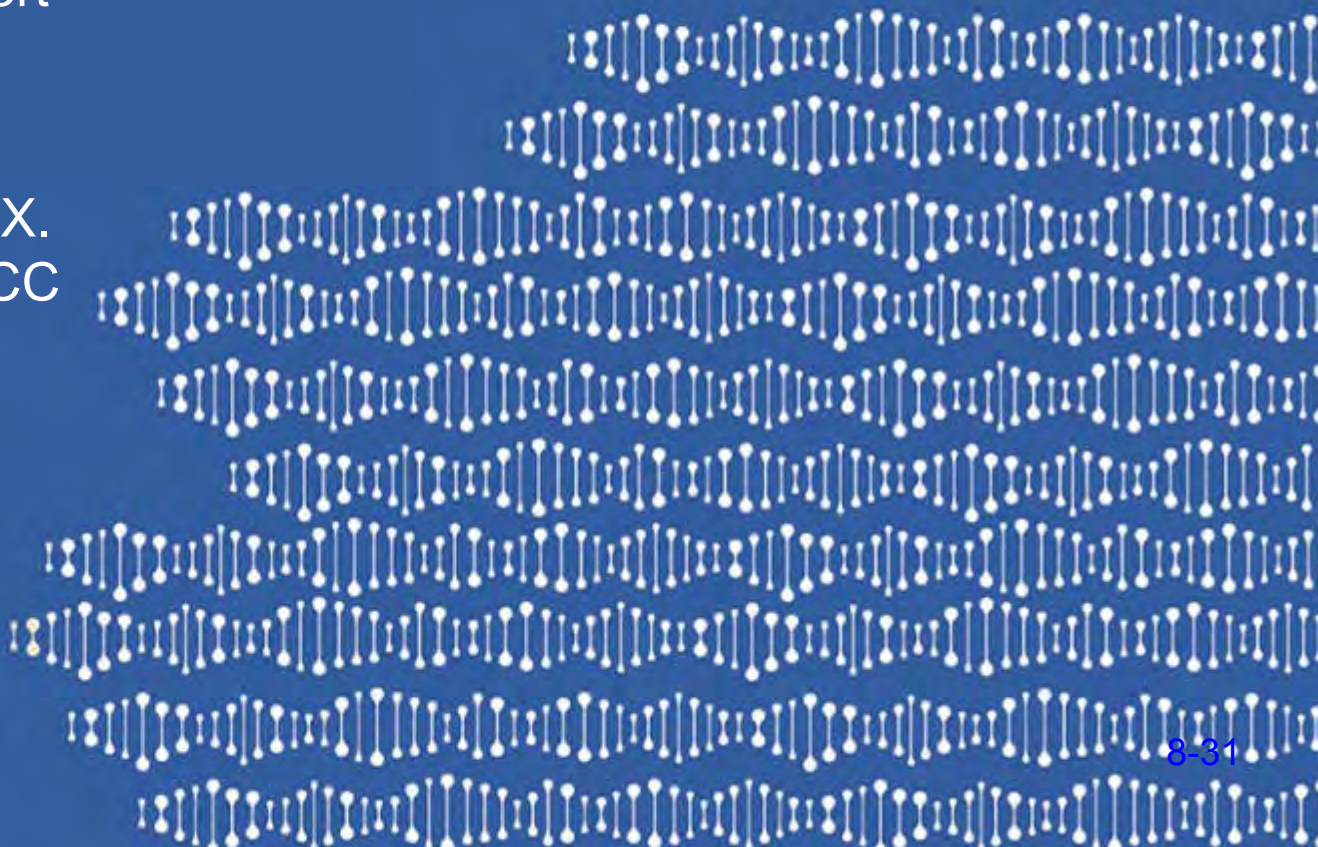
CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

Advisory Committee on Childhood Cancer

Committee Annual Report

February 21, 2019

Presented By: Stephen X. Skapek, MD, Chair, ACCC



CPRIT Advisory Committee on Childhood Cancer (ACCC)

- Composition and Distribution
- Childhood Cancer:
  - Current Status and Challenges
- Highlights and Progress
- ACCC Recommendations
- Summary

ACCC Composition and Representation

ACCC Membership

MEMBER	INSTITUTION	MEMBER	INSTITUTION
Stephen Skapek, MD	UT Southwestern	Lisa Hartman, MD	El Paso Children's Texas Tech HSC
Karen Albritton, MD	Cook Children's	Barkat Hooda, MD	UTMB Galveston
Mohamad Al-Rahawan, MD, MPH	Texas Tech HSC	Eugenie Kleinerman, MD	MD Anderson CC
James Amatruda, MD, PhD	UT Southwestern	Annette Leslie*	Carson Leslie Foundation
Greg Aune, MD, PhD	UTHSC San Antonio	Julie Luke, CPNP	Methodist Children's
Carol Basso*	1 Million 4 Anna Foundation	David Polack, MD	Texas Children's Baylor College of Medicine
Juan Carlos Bernini, MD	Vannie Cook Jr. Clinic	Richard Gorlick, MD	MD Anderson CC
Tim Culliver*	Adam's Angels Ministry	D. Will Parsons, MD, PhD	Texas Children's Baylor College of Medicine
Meaghan Granger, MD	Cook Children's	Patrick Reynolds, MD, PhD	Texas Tech HSC
Stan Goldman, MD	Medical City Dallas	Sheila Thampi, MD	Children's of San Antonio Baylor College of Medicine
Virginia Harod, MD	Dell Children's	Gail Thomlinson, MD, PhD	UTHSC San Antonio

* Patient Advocate

ACCC Membership Spans Texas

Childhood Cancer: Current Status and Challenges

Childhood Cancer: Still a Big Problem

- The leading cause of death from disease in children*
- 14,000 new cases per year in US
- 1 in every 330 Americans develops cancer before age 20
- 1 in 750 20-year-olds alive in the US today is a survivor of childhood cancer

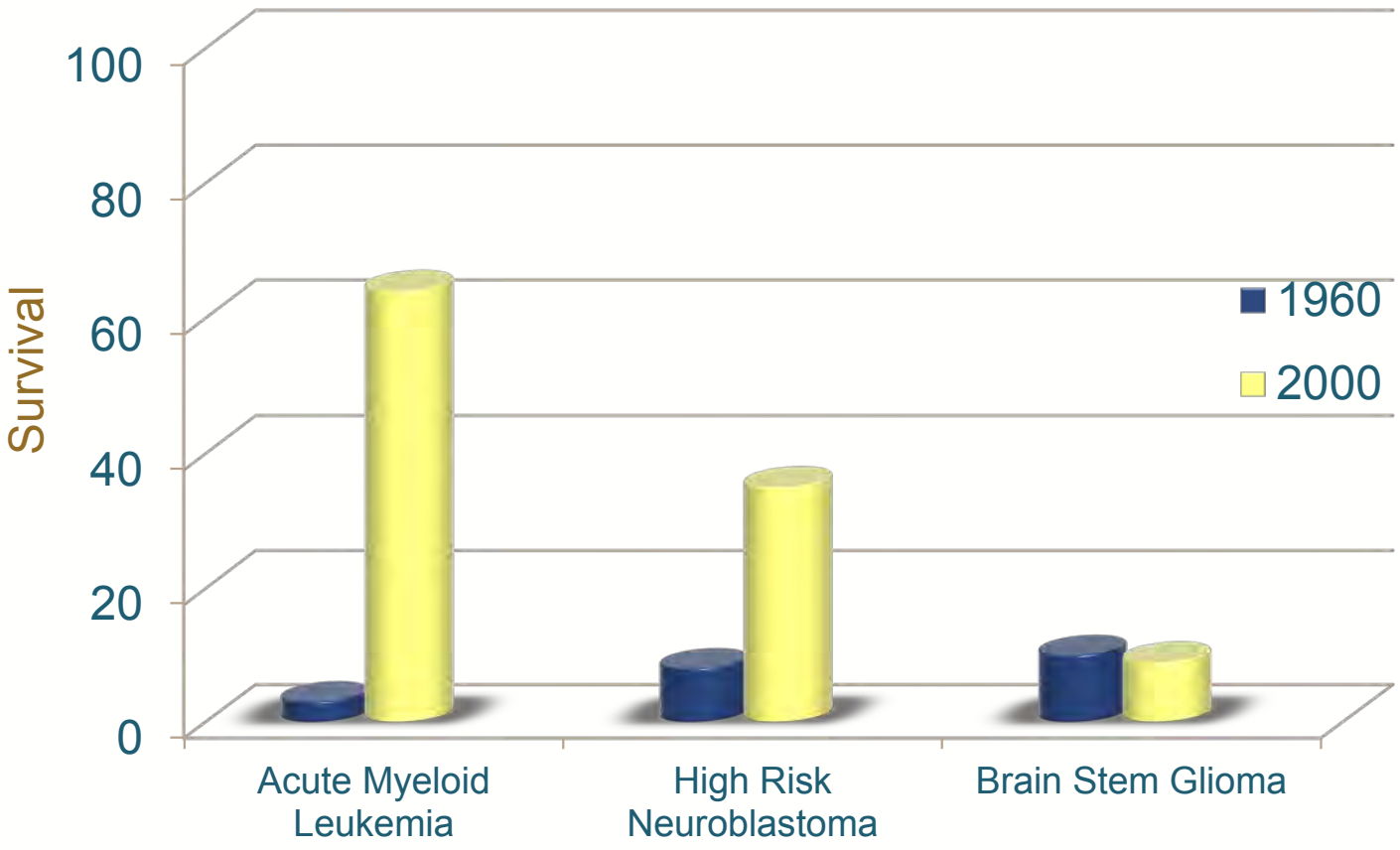
* 0 – 19 years of age

Childhood Cancer: Much progress…

Improved survival over 4 decades

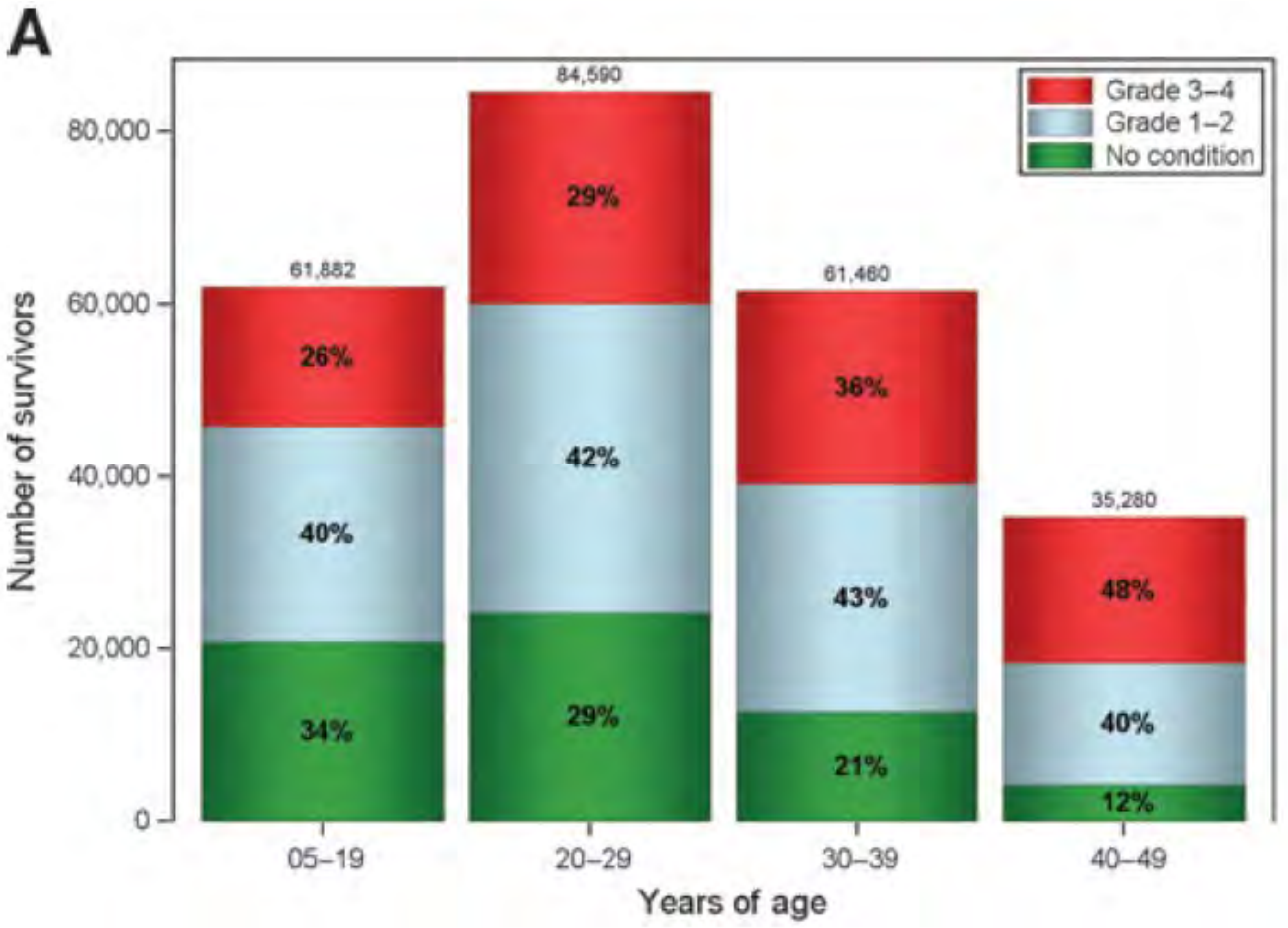
Childhood Cancer: … still much to do!

- High risk diseases still hard to control.



Childhood Cancer: Late effects of "cure"

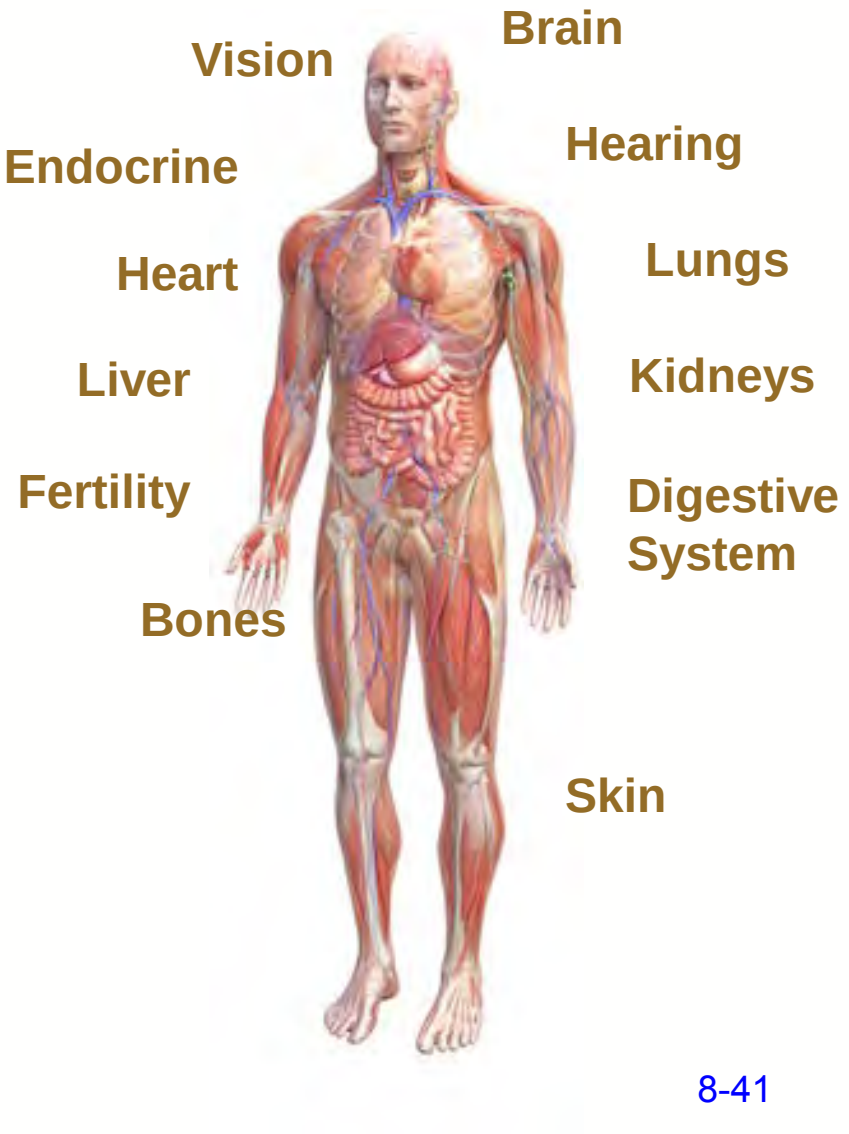
Most survivors of childhood cancer have long-term health problems



Philips et al, CEBP, 2015

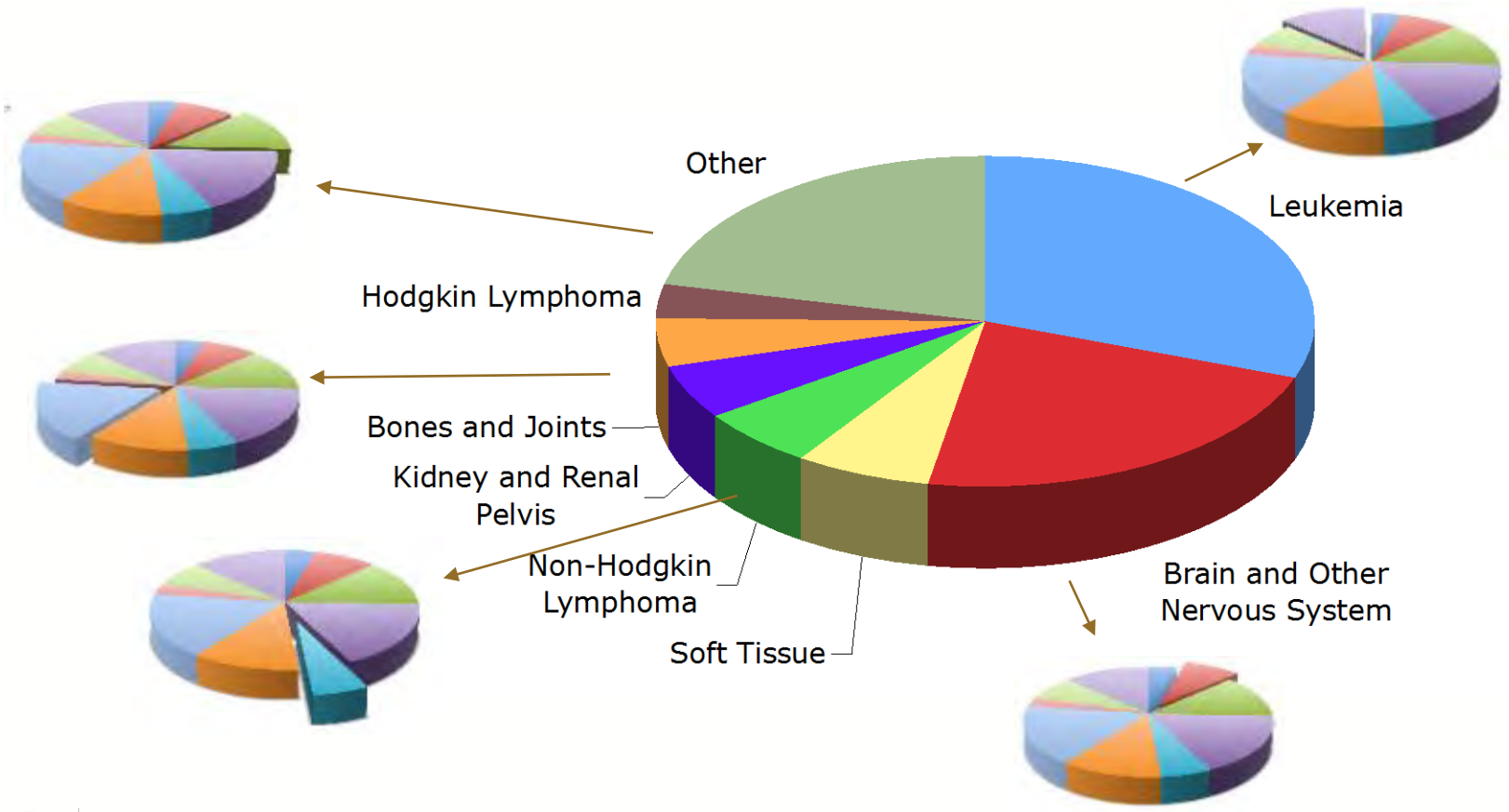
Childhood Cancer: Late effects of ”cure”

- Lasting medical problems affect many parts of the body



Childhood Cancer: Evolving definitions of cancer

New molecular classifications of cancer subtypes can help guide “precision” therapy



Childhood Cancer: Goals and challenges

- Improving survival in highest risk diseases
  - Molecularly-targeted therapy
  - Leveraging the immune system against the cancer
- Diminishing acute and lasting side effects
- Delivering treatment more “precisely”
- Developing better cancer control/prevention
- *Often limited access to new therapeutic agents*
- *Need for multi-institutional clinical studies*
- *Research funding*

Childhood Cancer Research Highlights/Progress

CPRIT Enables New Childhood Cancer Research

- *CPRIT funding has launched 150 research projects focused on childhood cancer*
  - More than $260 million dollars
  - Approximately 12% of CPRIT award portfolio

- *Independent research awards address important childhood cancer topics:*
  - Molecularly targeted therapies
  - Response biomarkers
  - Cancer metabolism
  - Immune surveillance
  - Mechanisms underlying heart toxicity
  - Cancer genetic susceptibility
  - Cancer prevention by HPV vaccine

CPRIT Enables New Childhood Cancer Research

- *Multi-investigator research awards catalyze "team science"*
  - *Pediatric Liver Cancer*
- *High-impact, high-risk awards realizing new opportunities*
  - *Targeting an "undruggable" oncogene: MYCN*
  - *Preventing colon cancer in childhood*
  - *Risk factors for leukemia*
- *Core Facilities create new resources*
  - *Pediatric Cancer Data Core*
  - *Pediatric solid tumor comprehensive data resource*

CPRIT Enables New Childhood Cancer Research

Recruiting new childhood cancer researchers in Texas

- John Powers, PhD, UT Austin
  - Genetic causes of neuroblastoma
- Kenneth Chen, MD
  - MicroRNAs and childhood kidney cancer

CPRIT Enables New Childhood Cancer Research

Pediatric clinical trials stemming from CPRIT Awards

- Eight active clinical research studies
- New drug therapies for childhood leukemia, kidney cancer, sarcoma
- New cellular immunotherapy for childhood leukemia
- New ways increase cancer prevention vaccine use

ACCC Recommendations

Continue to Support Childhood Cancer Research

- *Individual research awards focused on the following:*
  - Cancer in children and adolescents
  - Clinical translational research
  - Prevention and early detection
- *Core Facility Support Awards*
  - Consider including support for Texas-wide clinical research infrastructure
- *New and established faculty recruitment awards*
- *Multi-investigator research awards to catalyze interactions*

Continue Cancer Prevention Work

- *Applaud efforts to fund cancer prevention services in rural and medically-underserved areas*
- *Consider specific request for studies focused on early detection and cancer prevention in high-risk individuals, including cancer survivors*
- *Seek to expand portfolio to include projects focused on ways to improve health outcomes in childhood cancer survivors*

Focused Efforts on Clinical Trials

- *Seek innovation in Product Development Portfolio to facilitate and encourage drug and diagnostics development in childhood cancer.*

- *Consider providing Core Facility Support for clinical trials infrastructure for multi-institutional/state-wide trials.*

Summary

Summary

- *The ACCC applauds Texans for the forward-thinking development of CPRIT and supporting its visionary leadership that continues to embrace childhood cancer.*

- *Remarkable advances, including recent FDA approval of two new childhood cancer therapies, highlights how the field is on the cusp of even more breakthroughs.*

- *CPRIT support for childhood cancer research continues to position Texas to lead those efforts.*

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	CAMERON ECKEL, STAFF ATTORNEY
SUBJECT:	APPOINTMENTS TO THE SCIENTIFIC RESEARCH AND PREVENTION PROGRAMS COMMITTEE
DATE:	FEBRUARY 15, 2019

Summary and Recommendation

The Chief Executive Officer has appointed 10 experts to CPRIT's Scientific Research and Prevention Programs Committee. CPRIT's statute requires the appointments be approved by the Oversight Committee. The Nominations Subcommittee discussed the appointments at its meeting on February 15th and recommends that the Oversight Committee vote to approve the appointments.

Discussion

Scientific Research and Prevention Programs committee members (also referred to as "peer reviewers") are responsible for reviewing grant applications and recommending grant awards for meritorious projects addressing cancer prevention and research, including product development research. Peer reviewers perform an important role for the state; all CPRIT grant awards must first be recommended by a Scientific Research and Prevention Programs committee. Individuals appointed to serve as CPRIT's Scientific Research and Prevention Programs committee members must be exceptionally qualified, highly respected, well-established members of the cancer research, product development research, and prevention communities.

Texas Health and Safety Code Section 102.151(a) directs the Chief Executive Officer to appoint members to the Scientific Research and Prevention Programs committees. The CEO's appointments are final once approved by a simple majority of the Oversight Committee. The Nominations Subcommittee charter assigns the subcommittee with the responsibility "to circulate to Oversight Committee members in advance of a public meeting written notification of the committee's intent to make the nomination, along with such information about the nominee as may be relevant."

The Nominations Subcommittee considered the 10 pending peer reviewer appointments and recommends Oversight Committee approval.

Academic Research Peer Review Panels

- Graham Colditz, MD, DrPH
- Karen Emmons, Ph.D.
- Kim Lyerly, M.D.
- Katherine McGlynn
- Kirk Wangensteen, M.D., Ph.D.

Prevention Peer Review Panels

- Jasjit Singh Ahluwalia
- Deanna G.K. Teoh, M.D.

Product Development Peer Review Panels

- Anant Madabhushi
- Amy Trainor
- Bin Zheng

Nominations to Academic Research Peer Review Panels

- Graham Colditz, MD, DrPH
- Karen Emmons, Ph.D.
- Kim Lyerly, M.D.
- Katherine McGlynn
- Kirk Wangensteen, M.D., Ph.D.

BIOGRAPHICAL SKETCH

NAME: COLDITZ, GRAHAM A.

eRA COMMONS USER NAME: GCOLDITZ

POSITION TITLE: Niess-Gain Professor

EDUCATION/TRAINING

INSTITUTION AND LOCATION	DEGREE	Date	FIELD OF STUDY
University of Queensland, Brisbane	MBBS	12/1979	MB, BS (medicine)
Harvard TH Chan School of Public Health	DrPH (Doctor of Public Health)	06/1986	Epidemiology
Royal Australasian College of Physicians, Sydney, NSW	FAFPHM	06/1990	Fellow, Australian Faculty of Public Health Medicine
University of Queensland, Brisbane	Doctor of Medicine	01/1998	(PhD equivalent for physicians)

A. PERSONAL STATEMENT

I am an internationally recognized researcher and epidemiologist, particularly in the area of chronic disease prevention research. My body of research focuses on conducting large-scale longitudinal studies examining health, developing interactive risk assessment tools to provide tailored messages on the prevention of chronic diseases, and research synthesis & meta-analysis. I led the transdisciplinary studies of energetics and cancer center grant funded by NCI bringing investigators together across Washington University in St Louis. I added quality of life measures to the Nurses' Health Study follow-up and was funded to assess impact of breast cancer on function and aging in women (R01 AG014742). I have studied diet, physical activity and risk of osteoporotic fractures (RO1 AR0401383), and have led an NHLBI UO1 funded weight loss randomized pragmatic trial among low-income participants identified through Federally Qualified Health Centers in Boston; and led the WUSM site for the ENERGY trial, NCI funded randomized controlled trial of weight loss after breast cancer (serving as lead for the data center for the 4-site trial). I chaired the IARC workgroup on obesity and cancer in 2016. I have been continuously funded by NCI since 1987 and have an h-index over 220 (Scopus). I am a member of the National Academy of Medicine and serve on the NCI Board of Scientific Advisors. These experiences make me well qualified to contribute to this project linking environmental health to human health.

My dissemination and implementation sciences research includes colorectal cancer screening (funded by AHRQ then ACS as a translational innovation grant), adherence to guidelines, access to prevention services, and methods as summarized in books and journal articles. I am an editor (with Brownson and Proctor) of "*Dissemination and Implementation Research in Health: Translating Science to Practice*". Oxford University Press, 2012, second edition, 2017.

1. Emmons KM, **Colditz GA**. Realizing the Potential of Cancer Prevention - The Role of Implementation Science. N Engl J Med. 2017 Mar 9;376(10):986-990. PubMed PMID: 28273020; PubMed Central PMCID: PMC5473684.
2. **Colditz GA**, Emmons KM, Vishwanath K, Kerner JF. Translating science to practice: community and academic perspectives. J Public Health Manag Pract. 2008 Mar-Apr;14(2):144-9. PubMed PMID: 18287920.

B. POSITIONS AND HONORS

Positions and Employment

1983 - 2006 Epidemiologist, Brigham and Women's Hospital, Boston, MA
1998 - 2006 Professor (Medicine), Harvard Medical School, Boston, MA
1998 - 2006 Professor of Epidemiology, Harvard TH Chan School of Public Health, Boston, MA
2006 - Niess-Gain Professor, Washington University in Saint Louis, St Louis, MO

Other Experience and Professional Memberships

1993 -	Editorial Board Member, J Medical Screening
1997 - 1999	Editor, American Journal of Epidemiology
1998 - 2006	Editor-in-Chief, Cancer Causes and Control
2009 - 2014	Editorial Board, J Clinical Oncology
2015 -	Deputy Editor, Biostatistics, Annals of Thoracic Surgery

Honors

1981	Fulbright Scholar, Australian-American Fulbright Commission
1981	Frank Knox Fellow, Harvard University
2002	ACS Cissy Hornung Clinical Research Professor, American Cancer Society
2006	Member, Institute of Medicine (now National Academy of Medicine)
2007	Fellow, Academy of Science, St Louis
2009	Alumni Award, Harvard School of Public Health
2011	Medal of Honor, American Cancer Society
2012	AACR- ACS Award for Excellence in Cancer Epidemiology and Prevention, AACR
2014	American Cancer Society award and lecture, ASCO
2014	Award for outstanding achievement in cancer prevention research, AACR
2018	Daniel P. Schuster Award for Distinguished Work in Clinical and Translational Science, Washington University School of Medicine
2018	Fellow, American Association for the Advancement of Science

C. Contribution to Science

1. I identified current use of postmenopausal hormones as directly related to breast cancer risk and duration of use of estrogen plus progestin as again directly related to risk. This association was confirmed by the Women's Health Initiative RCT as a cause of breast cancer, and is classified as such by the IARC.
    a. **Colditz GA**, Stampfer MJ, Willett WC, Hennekens CH, Rosner B, Speizer FE. Prospective study of estrogen replacement therapy and risk of breast cancer in postmenopausal women. JAMA. 1990 Nov 28;264(20):2648-53. PubMed PMID: 2232041.
    b. **Colditz GA**, Hankinson SE, Hunter DJ, Willett WC, Manson JE, Stampfer MJ, Hennekens C, Rosner B, Speizer FE. The use of estrogens and progestins and the risk of breast cancer in postmenopausal women. N Engl J Med. 1995 Jun 15;332(24):1589-93. PubMed PMID: 7753136.
    c. **Colditz GA**. Decline in breast cancer incidence due to removal of promoter: combination estrogen plus progestin. Breast Cancer Res. 2007;9(4):108. PubMed PMID: 17666116; PubMed Central PMCID: PMC2206710.
2. I pioneered translation of epidemiological data to policy and practice and led implementation science in clinical medicine for colorectal screening and practice-based interventions to improve population health.
    a. Emmons KM, **Colditz GA**. Realizing the Potential of Cancer Prevention - The Role of Implementation Science. N Engl J Med. 2017 Mar 9;376(10):986-990. PubMed PMID: 28273020; PubMed Central PMCID: PMC5473684.
    b. Lobb R, **Colditz GA**. Implementation science and its application to population health. Annu Rev Public Health. 2013;34:235-51. PubMed PMID: 23297655; PubMed Central PMCID: PMC3901430.
    c. Emmons KM, Viswanath K, **Colditz GA.** The role of transdisciplinary collaboration in translating and disseminating health research: lessons learned and exemplars of success. Am J Prev Med. 2008 Aug;35(2 Suppl):S204-10. PubMed PMID: 18619401.
    d. Wei EK, Ryan CT, Dietrich AJ, **Colditz GA**. Improving colorectal cancer screening by targeting office systems in primary care practices: disseminating research results into clinical practice. Arch Intern Med. 2005 Mar 28;165(6):661-6. PubMed PMID: 15795343.
3. My research synthesis and comparative effectiveness contributions have helped shape public health policy and population health, including lung cancer screening guidelines.
    a. **Colditz GA**, Wolin KY, Gehlert S. Applying what we know to accelerate cancer prevention. Sci Transl Med. 2012 Mar 28;4(127):127rv4. PubMed PMID: 22461645; PubMed Central PMCID: PMC3343638.

b. **Colditz GA**, Berkey CS, Mosteller F, Brewer TF, Wilson ME, Burdick E, Fineberg HV. The efficacy of bacillus Calmette-Guérin vaccination of newborns and infants in the prevention of tuberculosis: meta-analyses of the published literature. Pediatrics. 1995 Jul;96(1 Pt 1):29-35. PubMed PMID: 7596718.
c. Wender R, Fontham ET, Barrera E Jr, **Colditz GA,** Church TR, Ettinger DS, Etzioni R, Flowers CR, Gazelle GS, Kelsey DK, LaMonte SJ, Michaelson JS, Oeffinger KC, Shih YC, Sullivan DC, Travis W, Walter L, Wolf AM, Brawley OW, Smith RA. American Cancer Society lung cancer screening guidelines. CA Cancer J Clin. 2013 Mar-Apr;63(2):107-17. PubMed PMID: 23315954; PubMed Central PMCID: PMC3632634.
d. Bach PB, Mirkin JN, Oliver TK, Azzoli CG, Berry DA, Brawley OW, Byers T, **Colditz GA**, Gould MK, Jett JR, Sabichi AL, Smith-Bindman R, Wood DE, Qaseem A, Detterbeck FC. Benefits and harms of CT screening for lung cancer: a systematic review. JAMA. 2012 Jun 13;307(22):2418-29. PubMed PMID: 22610500; PubMed Central PMCID: PMC3709596.

4. I showed that cigarette smoking increases risk of stroke in women while leading the Nurses' Health Study. I showed early age at menopause is related to heart disease risk. Subsequently, as PI of the overall cohort, I demonstrated relations of diet with fractures, and derived models for incidence of breast cancer, ovarian cancer, and melanoma.
   a. **Colditz GA**, Bonita R, Stampfer MJ, Willett WC, Rosner B, Speizer FE, Hennekens CH. Cigarette smoking and risk of stroke in middle-aged women. N Engl J Med. 1988 Apr 14;318(15):937-41. PubMed PMID: 3352685.
   b. Feskanich D, Hunter DJ, Willett WC, Hankinson SE, Hollis BW, Hough HL, Kelsey KT, **Colditz GA**. Vitamin D receptor genotype and the risk of bone fractures in women. Epidemiology. 1998 Sep;9(5):535-9. PubMed PMID: 9730033.
   c. Rosner BA, **Colditz GA**, Webb PM, Hankinson SE. Mathematical models of ovarian cancer incidence. Epidemiology. 2005 Jul;16(4):508-15. PubMed PMID: 15951669.
   d. Rosner BA, **Colditz GA**, Hankinson SE, Sullivan-Halley J, Lacey JV Jr, Bernstein L. Validation of Rosner-Colditz breast cancer incidence model using an independent data set, the California Teachers Study. Breast Cancer Res Treat. 2013 Nov;142(1):187-202. PubMed PMID: 24158759; PubMed Central PMCID: PMC3825503.

5. I developed interactive web-based tools to translate risk prediction models to tailored prevention messages across a range of chronic conditions (www.siteman.wuslt.edu/ydr), and have validate prediction models.
   a. Haas JS, Baer HJ, Eibensteiner K, Klinger EV, St Hubert S, Getty G, Brawarsky P, Orav EJ, Onega T, Tosteson AN, Bates DW, **Colditz G**. A Cluster Randomized Trial of a Personalized Multi-Condition Risk Assessment in Primary Care. Am J Prev Med. 2017 Jan;52(1):100-105. PubMed PMID: 27639785; PubMed Central PMCID: PMC5167657.
   b. De Vito KM, Baer HJ, Dart H, Chiuve SE, Rimm EB, **Colditz GA**. Validation of a risk prediction tool for coronary heart disease in middle-aged women. BMC Womens Health. 2015 Nov 10;15:101. PubMed PMID: 26552598; PubMed Central PMCID: PMC4640388.
   c. Kim DJ, Rockhill B, **Colditz GA**. Validation of the Harvard Cancer Risk Index: a prediction tool for individual cancer risk. J Clin Epidemiol. 2004 Apr;57(4):332-40. PubMed PMID: 15135833.
   d. **Colditz GA**, Atwood KA, Emmons K, Monson RR, Willett WC, Trichopoulos D, Hunter DJ. Harvard report on cancer prevention volume 4: Harvard Cancer Risk Index. Risk Index Working Group, Harvard Center for Cancer Prevention. Cancer Causes Control. 2000 Jul;11(6):477-88. PubMed PMID: 10880030

Complete List of Published Work in My Bibliography: http://tinyurl.com/colditzg

D. RESEARCH SUPPORT

Ongoing Research Support

Grant Award (Colditz) 10/1/2006-9/30/2019 0.24
Breast Cancer Research Foundation $208,333 calendar
Childhood and adolescent lifestyle, intermediate markers and breast cancer risk
The focus of this project, the ANN Inc Award, is to identify risk factors and markers that will improve our ability to accurately assess breast cancer risk and recommend appropriate treatments. By studying women who have dense breasts, ductal carcinoma in situ (DCIS), or benign breast disease (BBD), we will better understand why they are at an increased risk for breast cancer and how we might effectively prevent development of invasive cancer through a more aggressive regimen of screening, treatment, and/or follow-up. This award, renewed

annually since 2004 supports studies of etiology of benign lesions and risk following diagnosis of these lesions.

P20CA192966 (Colditz) 9/9/2015-8/31/2019 0.9
National Institutes of Health $115,036 calendar
2/2 Addressing Rural Cancer Health Disparities: an SCC-SIUSM Partnership
The overall goal is to establish a highly integrated research and training collaboration focused on rural cancer health disparities between Southern Illinois University School of Medicine (SIUSM), an institution that serves the population of Downstate Illinois, a largely rural and socioeconomically disadvantaged region with significant cancer health disparities, and the Siteman Cancer Center at Washington University in St. Louis (SCC-WUSTL), an NCI-designated Cancer Center. The Partnership will build SIUSM's research capacity and success conducting NIH-funded cancer disparity research, while also enhancing SCC's rural cancer awareness, research and reach. By doing so, the Partnership will contribute to reducing the cancer health disparities that persist in rural populations.

R21CA216515 (Toriola) 9/1/2017-8/31/2019 0.24
National Institutes of Health $134,076 calendar
Rank Pathway and Mammographic Density in Mid-Life Women
We propose to investigate the associations RANK pathway biomarkers, and variations in RANK genes with mammographic density in post-menopausal mid-life women (ages 50 and 64). Further, we will investigate factors that influence post-menopausal mid-life women's intent to use a new chemoprevention drug.

U01CA206110 (Toriola/Colditz) 4/1/2016-3/31/2021 0.3
National Institutes of Health $237,171 calendar
Transdisciplinary Team Science in Colorectal Prognosis: The Colocare Study
We are building and expanding the ColoCare Study, the only existing cohort of colorectal cancer patients for whom clinical data, information on health behaviors, and universal biospecimens have been systematically collected at repeat time points; ColoCare is uniquely suited for the discovery of new biomarkers of colorectal cancer treatment response and prognosis, as well as research that elucidates the influence of health behaviors on treatment efficacy and toxicity, quality-of-life, recurrence, and survival. This unique, multiethnic cohort will be an incredible resource for the broader research community, given its suitability for a wide-range of studies with potentially significant and near-term clinical impact.

U01CA209861 (James) 7/1/2017-6/30/2019 0.36
National Institutes of Health $336,605 calendar
Reducing Rural Colon Cancer Disparities Through Multi-Level Intervention On Follow-Up After Abnormal Screening Tests
Rural areas of the United States face disparately high rates of colon cancer incidence and mortality. While colon cancer screening has increased recently, many people with a positive fecal blood test do not receive a complete follow-up diagnostic evaluation. We will partner with a rural healthcare system, where FOBT is commonly used. In the proposed work, we will assess pre-implementation conditions to "set the stage" for future intervention.

P30CA091842 (Eberlein) 8/2/2001-6/30/2020 2.4
National Institutes of Health $2,795,463 calendar
Cancer Center Support Grant
The Siteman Cancer Center at Barnes-Jewish Hospital and Washington University School of Medicine is a multidisciplinary cancer research facility. The goals of the Siteman Cancer Center are to foster research productivity, promote interaction and collaboration, and take maximum advantage of institutional strengths and unique scientific opportunities to advance cancer diagnosis, treatment, and prevention for our patients.

R25CA171994 (Brownson) 9/12/2013-8/31/2019 0.9
National Institutes of Health $299,018 calendar
Mentored Training for Dissemination and Implementation Research in Cancer
The overall goal for the training program is to develop the first of its kind, Mentored Training for Dissemination and Implementation Research in Cancer at Washington University in St. Louis.

R01CA190391 (Waters) 4/1/2015-3/31/2019 0.24
National Institutes of Health $245,208 calendar
Communicating Multiple Disease Risks: A Translation of Risk Prediction Science
The objective of this study is to translate epidemiological data about five major health consequences of insufficient physical activity (i.e., colon cancer, breast cancer [women], heart disease, diabetes, and stroke) into a visual display that conveys individualized risk estimates in a way that is understandable and meaningful to diverse lay audiences and motivates engagement in physical activity. We designed the study to enhance the applicability of the results to individuals with less formal education and those who are members of racial or ethnic minority groups because they are relatively underrepresented in risk communication research, yet are affected disproportionately by low numeracy and the negative effects of insufficient physical activity.

UL1TR000448 (Evanoff) 6/1/2012-5/31/2021 0.24
National Institutes of Health $8,230,354 calendar
Washington University Institute of Clinical and Translational Sciences
Co-Investigator: Dissemination and Implementation Research Core (DIRC)
The overall goal of this application is to promote the translation of scientific discoveries into improvements in human health. Our specific aims will transform our research support infrastructure to foster multidisciplinary clinical and translational research, expand and enhance clinical and translational research education programs, and promote communication and collaborative research with regional and national partners.

U01DK106583, National Institutes of Health 2015/07/01-2020/06/30
Sutcliffe, Siobhan/Colditz, Graham A. (Multi-PI)
LUTS Prevention in Adolescent Girls and Women Across the Lifespan
This study proposes to identify risk factors for LUTS (overweight/obesity, habitual amateur high impact physical activity, habitual intake of caffeinated, carbonated, and artificially-sweetened beverages, and traumatic events and abuse) in adolescent girls and young, reproductive age women.
Role: Multi-PI

R01DK103760, National Institutes of Health (NIDDKD) 2015/01/09-2020/07/31
Evanoff, Bradley (PI)
Worksite Interventions to Reduce Obesity and Diabetes Risk in Low SES Populations
This study will test scalable worksite interventions to reduce obesity and diabetes risk among low-income workers, a group at high risk for these disorders. We will test the use of targeted communications, mobile phone technology, and worker participation in the design of workplace obesity interventions. This pragmatic study will advance the long-term goal of reducing obesity and obesity-associated illnesses including diabetes.
Role: Co-Investigator

T32 CA190194-02, (Colditz G, James A, Multi-PI) 2014/09/24-2019/08/31
Postdoctoral Training in Cancer Prevention and Control

T32CA009621 (Gillanders, Eberlein, Colditz Multi-PI) 07/05/88-06/30/19
Surgical Oncology Basic Science and Translational Research Training Program

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: Karen M. Emmons, PhD

eRA COMMONS USER NAME (credential, e.g., agency login): Kemmons

POSITION TITLE: Professor of Social and Behavioral Science,
Harvard T.H. Chan School of Public Health

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
University of Illinois, Champaign, IL	B.A.	1982	Psychology
State University of New York, Stony Brook, NY	M.A.	1986	Clinical Psychology
State University of New York, Stony Brook, NY	Ph.D.	1988	Clinical Psychology

A. Personal Statement

I am and a Professor of Social and Behavioral Science at the Harvard T.H. Chan School of Public Health. I am a behavioral scientist with a strong track record of funded research in community-based approaches to cancer prevention in a variety of settings that serve disadvantaged populations, including low income housing and community health centers. My work targets a range of cancer risk factors, including nutrition, physical activity, sun exposure, tobacco and second-hand smoke exposure, and cancer screening. My research teams have included interdisciplinary perspectives on cancer risk reduction and health disparities, with a focus on multiple cancer risk behaviors. I have a strong track record as a mentor, and am a past recipient of a mid-career K award (1K05 CA124415-02, Dissemination Research to Reduce Cancer Disparities). My current work and writing focuses heavily on implementation science, particularly in community health settings, and I have been actively involved in national efforts to develop implementation research and training programs. For the past 5 years I have held full-time academic administrative positions, and have recently made the decision to return to my passion (community-based implementation research). I currently serve as the Faculty Director of the Community Engagement Program for Harvard's Clinical Translational Science Award.

B. Positions and Honors

Training and Employment:

1988-1989	Assistant Professor, University of Illinois College of Medicine
1989-1996	Assistant Professor Brown University School of Medicine
1994-1997	Assistant Professor, Dana-Farber Cancer Institute and Harvard School of Public Health
1997-2002	Associate Professor, Dana-Farber Cancer Institute and Harvard School of Public Health
2002-2013	Professor, Dana-Farber Cancer Institute and Harvard School of Public Health
2013-present	Adjunct Professor, Dana-Farber Cancer Institute and Harvard School of Public Health
2013-2016	Vice President of Research, Kaiser Permanente; Director, Kaiser Foundation Research Institute
2016- 2018	Dean, Academic Affairs, Harvard T.H. Chan School of Public Health
2016 -	Professor, Harvard T.H. Chan School of Public Health

Honors, Distinctions and National Service:

1982	"Excellence in Undergraduate Teaching" Honors Distinction, U. of Illinois at Champaign-Urbana
1992	Awarded "Young Investigator Award," Society of Behavioral Medicine
2000	Fellow status, Society of Behavioral Medicine
1998	Member, Academy of Behavioral Medicine Research
2004	Distinguished Research Mentor, Society of Behavioral Medicine
2005	Morse Distinguished Researcher Award. Dana-Farber Cancer Institute
2007-08	Hedwig van Ameringen Executive Leadership in Academic Medicine Program for Women \
2008	HSPH 2008 Mentoring Citation Award
2010	Society of Behavioral Medicine, Cancer SIG's 2009 Outstanding Senior Scientist Award
2010-11	President, Society of Behavioral Medicine
2011-2018	Member, Board of Scientific Advisors, National Cancer Institute
2012- 2015	Member, Dissemination and Implementation Review Group, Center for Scientific Review, National Institutes of Health
2015-2019	Faculty, Mentored Training in Dissemination and Implementation Research in Cancer, Washington University, NIH-funded T32 training grant.
2010 -	Faculty, Planning Group Member, and Host (2015), Training in Dissemination and Implementation Research in Health, National Institutes for Health
2016	Member, National Academy of Medicine

Editorial Boards:

Year	Role	Name of Journal
1996 - 1999	Associate Editor	Annals of Behavioral Medicine
2000	Associate Editor	Health Psychology

C. Contributions to Science

A key contribution of my work as a PI has been in enhancing the understanding and integration of social contextual factors in cancer prevention interventions for low income and under-resourced communities. Our work moved intervention research beyond testing interventions, to addressing mechanisms that impact on participants' ability to address their health behaviors. This work has been designed to improve the outcomes of cancer prevention interventions for communities facing significant health disparities by increasing the relevance and reducing the barriers to health behavior change. This body of work has effectively engaged communities as partners, and has led to significant changes in cancer prevention outcomes across a number of target areas. Our work and that of others has also led to an increased recognition of the importance of social context in health and health behavior change.

1. **Emmons KM**, Hammond SK, Fava JL, Velicer WF, Evans JL, Monroe AD. A randomized trial to reduce passive smoke exposure in low-income households with young children. *Pediatrics* 2001; 108(1):18-24.

2. Bennett G, McNeil LH, Wolin KY, Duncan DT, **Emmons, KM**. Safe to walk? Neighborhood safety and physical activity among public housing residents. *PloS Medicine*. 2007 Oct;4(10):1599-606; discussion 1607. PMCID: PMC2039759.

3. Shelton RC, McNeill, Puleo E, Wolin, KY, **Emmons KM**, Bennett GG. The association between social factors and physical activity among low-income adults living in public housing. Am J Public Health. 2011 Nov;101(11):2102-10. (Epub 2011 Feb 17. PMCID: PMC3193546.

4. Shelton RC, Puleo E, Bennett GG, McNeill LH, Goldman RE, **Emmons KM**, Racial discrimination and physical activity among low-income-housing residents. *Am J Prev Med*. 2009 Dec;37(6):541-5. PMCID: PMC2818664.

Another area in which I have made significant contributions as a PI has been in the development of effective cancer prevention treatments for cancer survivors. My team conducted the first smoking cessation intervention randomized clinical trials for childhood cancer survivors, following on our work demonstrating relatively high smoking prevalence among this medically vulnerable population. A peer-delivered cessation program doubled smoking cessation rates, and had a long-term impact. Subsequent work looked at strategies to maintain that level of success while using intervention approaches that could be scaled in survivorship programs throughout the country. This body of work has helped moved the field from a focus primarily on cancer treatment and late effects, to considering the importance of cancer prevention among survivors.

1. **Emmons KM**, Li F, Whitton J, Diller L, Mertens A, Robinson L. Predictors of smoking initiation and cessation among childhood cancer survivors: The childhood cancer survivor study. Journal of Clinical Oncology 2002; 20 (6):1608-16.

2. **Emmons KM**, Butterfield R, Puleo, E, Park, E, Mertens A, Gritz ER, Lahti, M, Li F. Smoking among participants in the childhood cancer survivor study cohort: The Partnership for Health Study. Journal of Clinical Oncology 2003; 21(2): 189-96.

3. **Emmons KM**, Puleo E, Park E, Mertens A, Gritz E, Butterfield R, Li F. Peer-delivered smoking counseling for childhood cancer survivors increases rate of cessation: The Partnership for Health Study. Journal of Clinical Oncology 2005 September 23(27):6516-6523.

4. **Emmons KM**, Puleo E, Mertens A, Gritz ER, Diller L, Li FP. Long-Term Smoking Cessation Outcomes Among Childhood Cancer Survivors in The Partnership for Health Study. Journal of Clinical Oncology. 2009, Jan: 27(1):52-60. Epub 2008 Dec 1. PMCID: PMC2645097.

I have conducted a significant body of research in the area of multiple behavior change, leading some of the early work to evaluate how change cross behavioral risk factor areas co-occurred. My team conducted a number of studies demonstrating the advantage of a multiple risk factor change approach across a range of settings, including worksites, health care and communities. This work addressed methodologic and analytic challenges. Our most recent work examined multiple cancer screening targets, an area that has received little attention.

1. **Emmons KM**, Cleghorn D, Tellez T, Greaney ML, Sprunck KM, Bastani R, Battaglia T, Michaelson J, Puleo E. Prevalence and implications of multiple cancer screening needs among community health center patients. *CCC*: 2011 Sep;22(9):1343-9 (Epub 2011 Jul 5).

2. **Emmons KM**, McBride CM, Puleo E, Pollak K, Marcus BH, Napolitano M, Clipp E, Onken J, Farraye FA, Fletcher R. Prevalence and Predictors of Multiple Behavioral Risk Factors for Colon Cancer. Preventive Medicine 2005 May; 40(5):527-534.

3. **Emmons KM**, McBride CM, Puleo E, Pollak KI, Clipp E, Kuntz K, Marcus BH, Napolitano M, Onken J, Farraye F, Fletcher R. Project PREVENT: A randomized trial to reduce multiple behavioral risk factors for colon cancer. Cancer Epidemiology, Biomarkers and Prevention 2005; 14:1453-1459.

4. **Emmons KM**, Puleo E, Greaney ML, Gillman MW, Bennett GG, Haines J, Sprunck-Harrild K, Viswanath K. A randomized comparative effectiveness study of Healthy Directions 2—a multiple risk behavior intervention for primary care. Prev Med. 2014 Jul;64:96-102.

My work always focused on the intersection between identifying the most effective yet scalable intervention approaches because of the dissemination and implementation challenges facing us. I received one of the first dissemination supplements from NCI, which led to a continued effort to participate in the development of the field of Dissemination and Implementation Science. My work has focused on developing strategies to adapting evidence-based interventions for dissemination by peer leaders and in the context of community-based organizations and community care delivery settings, as well as addressing measurement issues in implementation science. I have also been

actively engaged in mentoring and service related to NIH programs in implementation science D.

1. Kerner J, Rimer B, **Emmons KM**, Dissemination Research and Research Dissemination: How Can We Close the Gap?, Health Psychology 2005;24(5);443-446.

2. Glasgow RE, **Emmons KM**. How can we increase translation of research into practice? Types of evidence needed. Annual Reviews of Public Health 2007 Apr;28: 413-433. Epub 2006 Dec 6.

3. **Emmons KM**, Weiner B, Fernandez M, Tu SP. Systems antecedents for dissemination and implementation. *Health Educ Behav*. 2012 Feb 39:87-105.

4. **Emmons KM**, Colditz GA. Realizing the Potential of Cancer Prevention - The Role of Implementation Science. N Engl J Med. 2017 Mar 9; 376(10):986-990.

Additional Information: Research Support and/or Scholastic Performance

Research Projects Completed During the Last 5 Years

5R01 CA126596-05 (Emmons) NIH/NCI 09/30/07 – 07/31/13
A Sustainable Approach to Increasing Cancer Screening in Community Health Centers
This study evaluated sustainable strategies for maximizing cancer-screening rates

5R01 CA123228-05 (Emmons) NIH/NCI 09/30/07 – 07/31/13
Multiple Risk Behavior Intervention in Health Care Settings
Healthy Directions was a cancer prevention intervention designed to reduce behavioral risk factors for cancer among working class, multi-ethnic adults in the health care setting.

5K05 CA124415-05 (Emmons) NIH/NCI 09/21/07 – 07/31/13
Dissemination Research to Reduce Cancer Disparities
This proposal focused on development of a conceptual model as the basis of developing a future program in dissemination research, related to reduction of cancer disparities.

5P50 CA127003-05 (Fuchs) NIH/NCI 07/01/07 – 06/30/13
DF/HCC SPORE in Gastrointestinal Cancer
This project was a dose-finding study to establish the optimal dose of vitamin D supplementation to be used in intervention studies focused on reducing disparities in vitamin D levels among Black adults. This study was conducted as a substudy to 5R01CA098864-05, Colon Cancer Prevention in Low Income Housing.

RR025758-04 (Nadler) Harvard Medical School 05/01/11 – 04/30/13
Clinical and Translational Science Award
I served as the Director of the Community Engagement Program for Harvard Catalyst. In this role I oversaw its community engagement activities, including its Community Advisory Board, its pilot research program, and its collaboration with the Massachusetts Department of Public Health, focused on translation of scientific evidence to policy.

5U54 CA156732-02 (Emmons/Prigerson (2012-15)) NIH/NCI 09/27/10 – 08/31/13
U Mass Boston / DFHCC U54 Partnership
This research initiative further developed our comprehensive partnership between the University of Massachusetts Boston (UMB) and the Dana-Farber/Harvard Cancer Center (DFHCC). The goal was to address health disparities in minority populations; to improve research in basic, clinical, and population science; and to provide training, research, and outreach opportunities for minority students, nurses, and scientists.

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. DO NOT EXCEED FIVE PAGES.

NAME: McGlynn, Katherine Ann

eRA COMMONS USER NAME (credential, e.g., agency login):

POSITION TITLE: Senior Investigator

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE (if applicable)	END DATE MM/YYYY	FIELD OF STUDY
Drew University, Madison, NJ	BA	05/1974	History
Tulane University, New Orleans, LA	MPH	05/1976	Population Studies
University of Pennsylvania, Philadelphia, PA	PHD	05/1984	Epidemiology

A. Personal Statement

My epidemiologic research on liver cancer spans my entire career beginning with my doctoral dissertation. I was initially drawn to liver cancer as it is a greatly understudied cancer, has an infectious etiology, and occurred disproportionally among underserved and margnizalized populations. My breadth of experience and interest in liver cancer will be an important asset for this project, as I would be sharing my expertise through various meetings with researchers in Mexico as well as visiting the biobank labs at the National Institute of Public Health, Mexico. My initial research, based on a large field study, was among Southeast Asian refugee populations receiving care at the Philadelphia Department of Health. This effort taught me a great deal about field logistics, the handling of biospecimens and the poverty and distress of underprivileged populations coping with hepatitis B infection and cancer. I used this knowledge in liver cancer studies in China and Africa before joining the NCI Intramural Program in 1998. As an intramural scientist, I have continued monitoring incidence and mortality of liver cancer around the world and have tracked the increasing rates of liver cancer in many locations. In the U.S., as elsewhere, liver cancer is more common among minority populations, and persons of lower-socioeconomic status. The steeply rising rates among Hispanics in the U.S. are a particularly troubling trend. In parallel with the high risk among U.S. Hispanics are the very high rates of liver cancer in the four low-and-middle income countries Central America.

B. Positions and Honors

Positions and Employment

1975 - 1976	Social Counselor, Charity Hospital, New Orleans, LA
1976 - 1976	Biostatistics Assistant , Department of Health Measurement Sciences, School of Public Health and Tropical Medicine, Tulane University, New Orleans, LA
1976 - 1977	Research Epidemiologist, Epidemiology Section, Department of Medicine, Tulane University Medical School,, New Orleans, LA
1977 - 1979	Research Assistant, MRFIT Heart Study, Department of Epidemiology and Preventive Medicine, University of Maryland Medical School, Baltimore, MD
1981 - 1982	Epidemiology Consultant, Institute for Cancer Research, Fox Chase Cancer Center, Philadelphia, PA
1983 - 1984	Research Assistant, Institute for Cancer Research, Fox Chase Cancer Center, Philadelphia, PA
1985 - 1988	Research Epidemiologist, Institute for Cancer Research, Fox Chase Cancer Center, Philadelphia, PA
1988 - 1990	Assistant Member, Fox Chase Cancer Center, Philadelphia, PA
1990 - 1998	Associate Member, Fox Chase Cancer Center, Philadelphia, PA
1994 - 1998	Adjunct Scholar, Center for Clinical Epidemiology and Biostatistics, University of Pennsylvania, Philadelphia, PA

1998 - 2008	Investigator, HREB, DCEG, NCI, NIH, Rockville, MD
2008 - 2015	Senior Investigator, HREB, DCEG, NCI, NIH, Rockville, MD
2011 - 2015	Deputy Branch Chief, HREB, DCEG, NCI, NIH, Rockville, MD
2016 -	Senior Investigator, MEB, DCEG, NCI, NIH, Rockville, MD

Other Experience and Professional Memberships

1985 -	Member, Society for Epidemiologic Research
1999 -	Member, American Association for Cancer Research
2006 -	Fellow, The American College of Epidemiology
2016 -	Member, Veterans Affairs Research Advisory Committee on Gulf War Veteran's Illnesses

Honors

2006	Fellow, American College of Epidemiology
2006	NIH Office of Rare Diseases Award, NIH
2006	NIH Merit Award, NIH
2006	DCCPS On-the-Spot Award for contributions as a Liver Cancer Expert, NCI
2010	Member, American Epidemiological Society
2010	Outstanding Mentor Award, NIH
2016	Mentoring Award, DCEG, NCI, NIH
2018	NIH Women Scientists' Outstanding Mentoring Award

C. Contribution to Science

1. Risk Factors for Liver Cancer in the U.S. In contrast to the declining incidence rates in high-risk areas, HCC incidence rates have been increasing in lower-risk areas, such as the U.S. since 1980. While some portion of the increase is related to HCV, since the early 1990s, the rate of new HCV infections has dropped substantially. While alcohol and some rare genetic disorders (e.g., hemochromatosis, a1-antirypsin deficiency, etc.) will continue to contribute to risk in a small way, the most important risk factor for the future is likely to be a constellation of metabolic disorders: obesity, diabetes, metabolic syndrome and non-alcoholic fatty liver disease (NAFLD). To examine the contribution of various risk factors in the US, I have conducted studies using the SEER-Medicare linked database to calculate attributable risks. I have also established a large liver cancer pooling project of U.S. based cohorts in order to examine risk factors directly.

    a. McGlynn KA, Sahasrabuddhe VV, Campbell PT, Graubard BI, Chen J, Schwartz LM, Petrick JL, Alavanja MC, Andreotti G, Boggs DA, Buring JE, Chan AT, Freedman ND, Gapstur SM, Hollenbeck AR, Hou L, King LY, Koshiol J, Linet M, Palmer JR, Poynter JN, Purdue M, Robien K, Schairer C, Sesso HD, Sigurdson A, Wactawski-Wende J, Zeleniuch-Jacquotte A. Reproductive factors, exogenous hormone use and risk of hepatocellular carcinoma among US women: results from the Liver Cancer Pooling Project. Br J Cancer. 2015 Mar 31;112(7):1266-72. PubMed PMID: 25742475; PubMed Central PMCID: PMC4385955.

    b. Petrick JL, Freedman ND, Graubard BI, Sahasrabuddhe VV, Lai GY, Alavanja MC, Beane-Freeman LE, Boggs DA, Buring JE, Chan AT, Chong DQ, Fuchs CS, Gapstur SM, Gaziano JM, Giovannucci EL, Hollenbeck AR, King LY, Koshiol J, Lee IM, Linet MS, Palmer JR, Poynter JN, Purdue MP, Robien K, Schairer C, Sesso HD, Sigurdson AJ, Zeleniuch-Jacquotte A, Wactawski-Wende J, Campbell PT, McGlynn KA. Coffee Consumption and Risk of Hepatocellular Carcinoma and Intrahepatic Cholangiocarcinoma by Sex: The Liver Cancer Pooling Project. Cancer Epidemiol Biomarkers Prev. 2015 Sep;24(9):1398-406. PubMed PMID: 26126626; PubMed Central PMCID: PMC4576990.

    c. Welzel TM, Graubard BI, Zeuzem S, El-Serag HB, Davila JA, McGlynn KA. Metabolic syndrome increases the risk of primary liver cancer in the United States: a study in the SEER-Medicare database. Hepatology. 2011 Aug;54(2):463-71. PubMed PMID: 21538440; PubMed Central PMCID: PMC4141525.

d. Welzel TM, Graubard BI, Quraishi S, Zeuzem S, Davila JA, El-Serag HB, McGlynn KA. Population-attributable fractions of risk factors for hepatocellular carcinoma in the United States. Am J Gastroenterol. 2013 Aug;108(8):1314-21. PubMed PMID: 23752878; PubMed Central PMCID: PMC4105976.

2. Pharmacoepidemiology studies of liver cancer. As metabolic disorders are strongly related to the development of HCC, I have initiated studies to determine whether medication used for metabolic disorders ameliorate the risk of HCC. These studies have primarily been conducted in the Clinical Practice Research Datalink of the United Kingdom.

   a. Hagberg KW, McGlynn KA, Sahasrabuddhe VV, Jick S. Anti-diabetic medications and risk of primary liver cancer in persons with type II diabetes. Br J Cancer. 2014 Oct 28;111(9):1710-7. PubMed PMID: 25093492; PubMed Central PMCID: PMC4453721.
   b. McGlynn KA, Hagberg K, Chen J, Graubard BI, London WT, Jick S, Sahasrabuddhe VV. Statin use and risk of primary liver cancer in the Clinical Practice Research Datalink. J Natl Cancer Inst. 2015 Apr;107(4)PubMed PMID: 25722350; PubMed Central PMCID: PMC4351398.
   c. McGlynn KA, Hagberg K, Chen J, Braunlin M, Graubard BI, Suneja N, Jick S, Sahasrabuddhe VV. Menopausal hormone therapy use and risk of primary liver cancer in the clinical practice research datalink. Int J Cancer. 2016 May 1;138(9):2146-53. PubMed PMID: 26662112; PubMed Central PMCID: PMC4764427.
   d. Yang B, Hagberg KW, Chen J, Sahasrabuddhe VV, Graubard BI, Jick S, McGlynn KA. Associations of antibiotic use with risk of primary liver cancer in the Clinical Practice Research Datalink. Br J Cancer. 2016 Jun 28;115(1):85-9. PubMed PMID: 27219020; PubMed Central PMCID: PMC4931369.

3. Incidence, mortality and survival of liver cancer. Patterns of liver cancer incidence, mortality and survival have been Liver cancer incidence rates have been rapidly increasing over the past 30 years. As liver cancer has a poor prognosis, examination of the rates could help to inform prevention and treatment strategies to reduce the incidence and burden of liver cancer. This quantification of rates is needed as individuals born between 1945 and 1965, who have the highest rates of infection with hepatitis C virus, are aging and becoming increasing higher risk for developing liver cancer.

   a. Altekruse SF, Petrick JL, Rolin AI, Cuccinelli JE, Zou Z, Tatalovich Z, McGlynn KA. Geographic variation of intrahepatic cholangiocarcinoma, extrahepatic cholangiocarcinoma, and hepatocellular carcinoma in the United States. PLoS One. 2015;10(3):e0120574. PubMed PMID: 25837669; PubMed Central PMCID: PMC4383424.
   b. Makarova-Rusher OV, Altekruse SF, McNeel TS, Ulahannan S, Duffy AG, Graubard BI, Greten TF, McGlynn KA. Population attributable fractions of risk factors for hepatocellular carcinoma in the United States. Cancer. 2016 Jun 1;122(11):1757-65. PubMed PMID: 26998818; PubMed Central PMCID: PMC5548177.
   c. Petrick JL, Kelly SP, Altekruse SF, McGlynn KA, Rosenberg PS. Future of Hepatocellular Carcinoma Incidence in the United States Forecast Through 2030. J Clin Oncol. 2016 May 20;34(15):1787-94. PubMed PMID: 27044939; PubMed Central PMCID: PMC4966339.
   d. Valery PC, Laversanne M, Clark PJ, Petrick JL, McGlynn KA, Bray F. Projections of primary liver cancer to 2030 in 30 countries worldwide. Hepatology. 2017 Aug 31;PubMed PMID: 28859220; PubMed Central PMCID: PMC5832532.

D. Additional Information: Research Support and/or Scholastic Performance

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: **LYERLY, HERBERT KIM**

eRA COMMONS USER NAME (credential, e.g., agency login): lyerly

POSITION TITLE: George Barth Geller Professor of Cancer Research

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
University of California, Riverside, California	BS	06/1980	Biomedical Sciences
University of California, Los Angeles, California	MD	06/1983	Medicine
Duke University, Durham, NC	Resident	05/1985	Surgery
Duke University, Durham, NC	Postdoctoral Fellow	06/1987	Micro/Immunology
Duke University, Durham, NC	Resident	06/1990	
Duke University, Durham, NC	Postdoctoral Fellow	06/1991	Molecular Biology

A. Personal Statement

Dr. Herbert Kim Lyerly is the George Barth Geller Professor of Cancer Research, Professor of Surgery and Immunology and Associate Professor of Pathology at Duke University. Dr. Lyerly has a 30-year history of translational research in cancer immunotherapy focusing on T-cell responses to tumor antigens. He has maintained an active research laboratory while providing administrative support for large, complex, multi-investigator grants from the National Cancer Institute and the US Department of Defense. Dr. Lyerly has served as a presidential appointee to the National Cancer Advisory Board. He has served as the Principle Investigator (PI) of the Duke Breast Cancer Spore from 2003 to 2010, and as the Director and PI of the Duke Comprehensive Cancer Center Core grant from 2003 - 2011. Dr. Lyerly currently is the PI of 3 Department of Defense research grants focusing on earlier detection of breast cancer, the genomics of early stage breast cancer and cancer vaccines targeting breast cancer. Dr. Lyerly will serve as the PI of a submitted Duke SPORE in Breast Cancer application as well as the co-director of the Administrative Core of the Duke SPORE in breast cancer. Dr. Lyerly will also serve as the co-investigator on a SPORE translational research project focusing on immunotherapy of breast cancer.

B. Positions and Honors

Positions and Employment

1990 - 1994 Assistant Professor, Department of Surgery, Duke University Medical Center, Durham, NC
1991 - 1998 Assistant Professor, Department of Pathology, Duke University Medical Center, Durham, NC
1994 - 1997 Associate Professor, Department of Surgery, Duke University Medical Center, Durham, NC
1998 - 2018 Associate Professor, Department of Pathology, Duke University Medical Center, Durham, NC
1997 - Professor, Department of Surgery, Duke University Medical Center, Durham, NC
1995 - 2016 Assistant Professor, Department of Immunology, Duke University Medical Center, Durham, NC
2003 - 2011 Director, Duke Comprehensive Cancer Center, Duke University Medical Center, Durham, NC
2004 - George Barth Geller Professor of Cancer Research, Duke University, Durham, NC
2012 - Director, Center for Applied Therapeutics, Duke University Medical Center, Durham, NC
2012 - 2014 Visiting Professor, Beijing University of Technology
2012 - 2017 Co-Director, Capital Medical School Cancer Center, Beijing, China

2014 - 2015 Visiting Professor, Shaanxi Provincial Cancer Hospital, Xian
2017 - Professor, Department of Immunology, Duke University Medical Center, Durham, NC
2018 - Professor, Department of Pathology, Duke University Medical Center, Durham, NC

Other Experience and Professional Memberships

1991 - 2015 Fellow, American College of Surgeons
2003 - 2015 Director, Accelerating Anticancer Agent Development and Validation Workshop
2008 - Advisory Commission Member, North Carolina State Museum of Natural Sciences
2008 - 2011 Chair, Cancer Centers Subcommittee, National Cancer Advisory Board
2008 - 2014 Member, National Cancer Advisory Board, National Cancer Institute

Honors

1983 Alpha Omega Alpha, University of California, Los Angeles
1987 Weck Resident Award, Duke University Medical Center
1987 Resident Achievement Award, American College of Surgeons
1991 Sigma XI, Duke University Medical Center
2010 Susan G. Komen Scholar, Susan G. Komen Foundation
2014 Director's Service Award, National Cancer Institute

C. Contributions to Science

1. I have been involved in research and the development of understanding of the role of human retroviral infections, particularly human immunodeficiency virus (HIV) in human disease. As an investigator, I studied molecular mechanisms of viral entry into immune cells, as well as identifying mechanisms of immune recognition and attack. This work resulted in advancing understanding of HIV infection and the development of novel therapeutic and preventative strategies.

    a. Chen H, Boyle TJ, Malim MH, Cullen BR, Lyerly HK. Derivation of a biologically contained replication system for human immunodeficiency virus type 1. Proc Natl Acad Sci U S A. 1992 Aug 15;89(16):7678-82. PubMed PMID: 1502183; PubMed Central PMCID: PMC49774.
    b. Hwang SS, Boyle TJ, Lyerly HK, Cullen BR. Identification of the envelope V3 loop as the primary determinant of cell tropism in HIV-1. Science. 1991 Jul 5;253(5015):71-4. PubMed PMID: 1905842.
    c. Lyerly HK, Matthews TJ, Langlois AJ, Bolognesi DP, Weinhold KJ. Human T-cell lymphotropic virus IIIB glycoprotein (gp120) bound to CD4 determinants on normal lymphocytes and expressed by infected cells serves as target for immune attack. Proc Natl Acad Sci U S A. 1987 Jul;84(13):4601-5. PubMed PMID: 3037522; PubMed Central PMCID: PMC305138.
    d. Yarchoan R, Klecker RW, Weinhold KJ, Markham PD, Lyerly HK, Durack DT, Gelmann E, Lehrman SN, Blum RM, Barry DW. Administration of 3'-azido-3'-deoxythymidine, an inhibitor of HTLV-III/LAV replication, to patients with AIDS or AIDS-related complex. Lancet. 1986 Mar 15;1(8481):575-80. PubMed PMID: 2869302.

2. I have been involved in identifying immune based strategies for the targeting of cancer. I made the original observation that virally infected and transformed B-cells could be recognized by Epstein bar virus specific T-cells in a human tumor model. This work lead to the development of adaptive immunotherapy strategies in experimental animal models and human studies. The conceptual framework of viral antigens serving as cancer targets in specific antigen recognition based therapies is the basis for my ongoing research work.

    a. Boyle TJ, Tamburini M, Berend KR, Kizilbash AM, Borowitz MJ, Lyerly HK. Human B-cell lymphoma in severe combined immunodeficient mice after active infection with Epstein-Barr virus. Surgery. 1992 Aug;112(2):378-86. PubMed PMID: 1322566.
    b. Boyle TJ, Berend KR, DiMaio JM, Coles RE, Via DF, Lyerly HK. Adoptive transfer of cytotoxic T lymphocytes for the treatment of transplant-associated lymphoma. Surgery. 1993 Aug;114(2):218-25; discussion 226. PubMed PMID: 8393595.

c. DiMaio JM, Van Trigt P, Gaynor JW, Davis RD, Coveney E, Clary BM, Lyerly HK. Generation of tumor-specific T lymphocytes for the treatment of posttransplant lymphoma. Circulation. 1995 Nov 1;92(9 Suppl):II202-5. PubMed PMID: 7586409.

d. Li Y, Bendandi M, Deng Y, Dunbar C, Munshi N, Jagannath S, Kwak LW, Lyerly HK. Tumor-specific recognition of human myeloma cells by idiotype-induced CD8(+) T cells. Blood. 2000 Oct 15;96(8):2828-33. PubMed PMID: 11023518.

3. Since many cancers in humans are associated with known viral infections, I have tried to develop alternative strategies targeting cancer using the immune system. I began exploring the role of dendritic cells in cancer immunotherapy performed preclinical work, and first in human studies dendritic cell based vaccines and other antigen specific immunotherapies for the treatment of cancer.

a. Nair SK, Boczkowski D, Morse M, Cumming RI, Lyerly HK, Gilboa E. Induction of primary carcinoembryonic antigen (CEA)-specific cytotoxic T lymphocytes in vitro using human dendritic cells transfected with RNA. Nat Biotechnol. 1998 Apr;16(4):364-9. PubMed PMID: 9555728.

b. Morse MA, Coleman RE, Akabani G, Niehaus N, Coleman D, Lyerly HK. Migration of human dendritic cells after injection in patients with metastatic malignancies. Cancer Res. 1999 Jan 1;59(1):56-8. PubMed PMID: 9892184.

c. Mosca PJ, Hobeika AC, Clay TM, Nair SK, Thomas EK, Morse MA, Lyerly HK. A subset of human monocyte-derived dendritic cells expresses high levels of interleukin-12 in response to combined CD40 ligand and interferon-gamma treatment. Blood. 2000 Nov 15;96(10):3499-504. PubMed PMID: 11071647.

d. Nair SK, Morse M, Boczkowski D, Cumming RI, Vasovic L, Gilboa E, Lyerly HK. Induction of tumor-specific cytotoxic T lymphocytes in cancer patients by autologous tumor RNA-transfected dendritic cells. Ann Surg. 2002 Apr;235(4):540-9. PubMed PMID: 11923611; PubMed Central PMCID: PMC1422470.

4. I focused attention on developing immunotherapy strategies targeting oncogenic drivers of tumors, rather than differentially expressed antigens. An early strategy was to target the HER2 antigen, using a variety of novel immunotherapy strategies, and I performed pre-clinical and clinical studies demonstrating the immunogenicity of HER2 and it's potential in generating immune response that may have clinical benefit. This work is ongoing, utilizing emerging strategies to optimize immune responses and to eradicate immune checkpoints.

a. Morse MA, Hobeika A, Osada T, Niedzwiecki D, Marcom PK, Blackwell KL, Anders C, Devi GR, Lyerly HK, Clay TM. Long term disease-free survival and T cell and antibody responses in women with high-risk Her2+ breast cancer following vaccination against Her2. J Transl Med. 2007 Sep 6;5:42. PubMed PMID: 17822557; PubMed Central PMCID: PMC2042490.

b. Hartman ZC, Wei J, Osada T, Glass O, Lei G, Yang XY, Peplinski S, Kim DW, Xia W, Spector N, Marks J, Barry W, Hobeika A, Devi G, Amalfitano A, Morse MA, Lyerly HK, Clay TM. An adenoviral vaccine encoding full-length inactivated human Her2 exhibits potent immunogenicty and enhanced therapeutic efficacy without oncogenicity. Clin Cancer Res. 2010 Mar 1;16(5):1466-77. PubMed PMID: 20179231; PubMed Central PMCID: PMC2831125.

c. Morse MA, Wei J, Hartman Z, Xia W, Ren XR, Lei G, Barry WT, Osada T, Hobeika AC, Peplinski S, Jiang H, Devi GR, Chen W, Spector N, Amalfitano A, Lyerly HK, Clay TM. Synergism from combined immunologic and pharmacologic inhibition of HER2 in vivo. Int J Cancer. 2010 Jun 15;126(12):2893-903. PubMed PMID: 19856307; PubMed Central PMCID: PMC2856803.

d. Hartman ZC, Yang XY, Glass O, Lei G, Osada T, Dave SS, Morse MA, Clay TM, Lyerly HK. HER2 overexpression elicits a proinflammatory IL-6 autocrine signaling loop that is critical for tumorigenesis. Cancer Res. 2011 Jul 1;71(13):4380-91. PubMed PMID: 21518778; PubMed Central PMCID: PMC3129398.

5. I have used the laboratory and pre-clinical models to establish novel strategies and novel combinations to enhance immune responses that have been tested in first in human and phase II studies. This includes many first in human studies of the novel cellular and viral vaccines as well as novel combinations, including

recombinant viral vector modifications of dendritic cells , the use regulatory T-cell depletion to enhance T-cell responses, and the testing the utility of extending of these vaccine studies in the setting of minimal tumor burden to optimize the potential for immunotherapies to be clinically effective.

a. Morse MA, Clay TM, Hobeika AC, Osada T, Khan S, Chui S, Niedzwiecki D, Panicali D, Schlom J, Lyerly HK. Phase I study of immunization with dendritic cells modified with fowlpox encoding carcinoembryonic antigen and costimulatory molecules. Clin Cancer Res. 2005 Apr 15;11(8):3017-24. PubMed PMID: 15837756.
b. Morse MA, Hobeika AC, Osada T, Serra D, Niedzwiecki D, Lyerly HK, Clay TM. Depletion of human regulatory T cells specifically enhances antigen-specific immune responses to cancer vaccines. Blood. 2008 Aug 1;112(3):610-8. PubMed PMID: 18519811; PubMed Central PMCID: PMC2481547.
c. Morse MA, Hobeika AC, Osada T, Berglund P, Hubby B, Negri S, Niedzwiecki D, Devi GR, Burnett BK, Clay TM, Smith J, Lyerly HK. An alphavirus vector overcomes the presence of neutralizing antibodies and elevated numbers of Tregs to induce immune responses in humans with advanced cancer. J Clin Invest. 2010 Sep;120(9):3234-41. PubMed PMID: 20679728; PubMed Central PMCID: PMC2929723.
d. Morse MA, Niedzwiecki D, Marshall JL, Garrett C, Chang DZ, Aklilu M, Crocenzi TS, Cole DJ, Dessureault S, Hobeika AC, Osada T, Onaitis M, Clary BM, Hsu D, Devi GR, Bulusu A, Annechiarico RP, Chadaram V, Clay TM, Lyerly HK. A randomized phase II study of immunization with dendritic cells modified with poxvectors encoding CEA and MUC1 compared with the same poxvectors plus GM-CSF for resected metastatic colorectal cancer. Ann Surg. 2013 Dec;258(6):879-86. PubMed PMID: 23657083; PubMed Central PMCID: PMC3812363.

Complete List of Published Work in My Bibliography:
http://1.usa.gov/1PnGU3j

D. Additional Information: Research Support

Ongoing Research Support

W81XWH-12-1-0447, DoD Lyerly (PI) 09/30/12-09/29/18
Oncogenic Signaling Networks
We propose to detect and characterize oncogenic signaling nodes in breast cells in vivo, which will transform breast cancer diagnosis, characterization, treatment and ultimately prevention.

W81XWH-12-1-0574, DoD Lyerly (PI) 09/30/12-09/30/18
Developing a HER3 Vaccine to Prevent Resistance to Endocrine Therapy
The translational studies proposed here intend to generate a GMP version of our HER3 vaccine, test its safety and immunogenicity, and then first evaluate whether HER3 vaccination in combination with standard anti-hormonal therapy (exemestane) in an anti-hormonal resistant population leads to increased efficacy of the standard therapy.

W81XWH-14-1-0111, DoD Lyerly (PI) 09/30/14-09/29/19
A Molecular Framework for Understanding DCIS
The goal of this project is to build the foundations necessary for identification of prognostic biomarkers of progression, the development of strategies to prevent invasive disease, and choosing targets for immunoprophyla.

5R01CA172570, NIH Chen (PI) 09/19/13-07/31/18
Inhibition of Wnt/B-Catenin Signaling in Colorectal Cancer Therapy
The objective of this proposal is to identify the target and define the mechanism of niclosamide-mediated inhibition of Wnt signaling in order to inform clinical trial designs with niclosamide, and to reveal potential novel mechanisms contributing to the regulation of Wnt/B-catenin signaling in CRC. Furthermore, our study will

provide a biological target amenable to small molecule drug design, and to discover improved inhibitors that offer potential for greater clinical benefit.
Role: Co-Investigator

1R01-CA188177-01A1, NIH Vaidyanathan (PI) 05/01/15-04/30/20
Labeling Nanobodies with 18F Residualizing Labels for HER2 Specific PET Imaging
1) Develop prosthetic groups for F-Labeling of Nbs based on the best Nb radioiodination residualizing agent, N-succinimidyl 4-guanidinomethyl-3-[*I]iodobenzoate ([*I]SGMIB). 2) Label Nbs with these agents and determine the characteristics of the labeled Nb conjugates. 3) Evaluate labeled Nbs in vitro using HER2-expressing breast cancer cells. 4) Evaluate labeled Nbs in vivo in mice bearing breast carcinoma xenografts.
Role: Co-Investigator

Fred Hutch Cancer Research Center Lyerly (PI) 2/5/17-2/14/19
Investigating Adaptive Immune Recognition of Dormant Disseminated Tumor Cells
The overarching objective of this project is to determine whether the adaptive immune system can recognize and kill dormant DTC's, and if not, which aspect of DTC biology should be targeted to enhance cell recognition. The ultimate goal is to leverage the findings to develop approaches to eliminate dormant DTC's, prevent late recurrences, and reduce deaths from breast cancer.

2T32-CA093245-11A1, NIH Lyerly (PI) 9/1/16-8/31/21
Translational Research in Surgical Oncology
This training grant application seeks funding for the Duke Research Training Program in Surgical Oncology in the Duke University Department of Surgery. The unifying objective of the program will be to train the future national leaders in academic surgical oncology.

Completed Research Support

K12 CA100639-10 Lyerly (PI) 04/01/03-07/31/15
Clinical Oncology Research Career Development Program

P30 CA014236-36 Lyerly (PI) 09/03/10-12/31/14
Administration Core

4102-77493, Purdue University Lyerly (PI) 7/1/16-6/30/17
Advancing Immunology in Dogs with Naturally-occurring Invasive Bladder Cancer, a Relevant Model to Improve Immunotherapy Across Molecular Cancer Subtypes in Humans
We processed the DNA and RNA sequencing data to predict tumor antigens on canine bladder cancer cells. We also performed immunoproteomic analysis of canine cancer cell lines, immunoprecipitate canine class I MHC complexes with peptides, and identified peptides using mass spectroscopy and bioinformatics analysis. We then compared the predicted antigens based on DNA and RNA sequencing data with the actual antigens presented by peptide MHC complexes from canine bladder cancers.

1R33-CA191198-03, NIH Caron (PI) 2/9/15-1/31/18
A Cancer Rainbow Mouse for Simultaneous Assessment of Multiple Oncogenes
A Cancer Rainbow Mouse for Simultaneous Assessment of Multiple Oncogenes The Crainbow platform will decentralize mouse engineering thereby transforming mouse model development into a user-defined commodity accessible by most standard cancer research laboratories. Crainbow's unique ability to study multiple driver genes with cellular resolution and in a single mouse will transform lists of candidate drivers into validated molecular and cellular targets.

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. DO NOT EXCEED FIVE PAGES.

NAME: Wangensteen, Kirk

eRA COMMONS USER NAME (credential, e.g., agency login): wangensteen

POSITION TITLE: Assistant Professor of Medicine and Genetics

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE (if applicable)	END DATE MM/YYYY	FIELD OF STUDY
Northwestern University, Evanston, IL	BA	06/2000	Biological Sciences
University of Minnesota, Minneapolis, MN	PHD	01/2007	Biochem, Mol Bio, and Biophysics
University of Minnesota, Minneapolis, MN	MD	05/2009	Medicine
University of Vermont, Burlington, VT	Resident	06/2011	Internal Medicine
University of Pennsylvania, Philadelphia, PA	Postdoc	06/2012	Liver Biology and Genetics
University of Pennsylvania, Philadelphia, PA	Fellow	06/2015	Gastroenterology

A. Personal Statement

My areas of expertise are in liver biology, liver cancer (namely hepatocellular carcinoma, HCC), gastroenterology, and genetics. I focus on unraveling the genetic pathways that enable hepatocyte repopulation in the setting of liver injury and – in the setting of prolonged injuries or deregulation of oncogenes – lead to cancer.

HCC is prevalent worldwide, has a high mortality rate, and has few effective treatment options. Previous efforts to discover targets in HCC have relied on *in vitro* or low-throughput *in vivo* methods. My lab aims to discover new treatments by applying highly innovative approaches to mice including performing powerful genetic screens *in vivo* in the hepatocytes of the liver. We have already succeeded to perform a drug susceptibility screen to discover synergism between the only FDA-approved therapeutic for HCC, sorafenib, and a novel drug compound that activates a nuclear receptor, LXR. We are expanding on this approach to uncover additional targets.

I am a physician-scientist with 80% of my time devoted to research and 20% to caring for patients with gastrointestinal diseases including liver cancer, which is predominantly hepatocellular carcinoma (HCC). This devastating cancer has a 5-year survival rate of less than 18% according to the SEER database. Cure is possible by liver transplantation, but this is available to only a minority of patients as HCC is usually too advanced at the time it is detected. Current drug treatments improve survival by a median of only 2-3 months; thus, new treatment options are desperately needed. In the clinic, I perform diagnostic tests, conduct counseling, evaluate laboratory test results, recommend treatments, and complete genetic testing for mutations that predispose patients to developing gastrointestinal cancers. I often observe the destructive consequences of liver cancer and the severe impact on patients and their families. Indeed, the major driving force for my lab and clinic is to one day bring about new therapies that may offer patients sustained remission from HCC.

Key publications:

1. Kieckhaefer JE, Maina F, Wells R, **Wangensteen KJ**: Liver cancer gene discovery using gene targeting, *Sleeping Beauty*, and CRISPR/Cas9. Seminars in Liver Disease 2019 Notes: In press.
2. **Wangensteen KJ**, Wang YJ, Dou Z, Wang AW, Mosleh-Shirazi E, Horlbeck MA, Gilbert LA, Weissman JS, Berger SL, Kaestner KH. Combinatorial genetics in liver repopulation and carcinogenesis with a in vivo CRISPR activation platform. Hepatology. 2018 Aug;68(2):663-676. PubMed PMID: 29091290; PubMed Central PMCID: PMC5930141.
3. Dou Z, Ghosh K, Vizioli MG, Zhu J, Sen P, **Wangensteen KJ**, Simithy J, Lan Y, Lin Y, Zhou Z, Capell BC, Xu C, Xu M, Kieckhaefer JE, Jiang T, Shoshkes-Carmel M, Tanim KMAA, Barber GN, Seykora JT, Millar SE, Kaestner KH, Garcia BA, Adams PD, Berger SL. Cytoplasmic chromatin triggers inflammation in senescence and cancer. Nature. 2017 Oct 19;550(7676):402-406. PubMed PMID: 28976970; PubMed Central PMCID: PMC5850938.

4. **Wangensteen KJ**, Zhang S, Greenbaum LE, Kaestner KH. A genetic screen reveals Foxa3 and TNFR1 as key regulators of liver repopulation. Genes Dev. 2015 May 1;29(9):904-9. PubMed PMID: 25934503; PubMed Central PMCID: PMC4421979.

B. Positions and Honors

Positions and Employment

2015 - 2017 Instructor in Medicine, University of Pennsylvania Perelman School of Medicine, Philadelphia, PA

2018 - Assistant Professor of Medicine and Genetics, University of Pennsylvania Perelman School of Medicine, Philadelphia, PA

Other Experience and Professional Memberships

2010 - Field Partner, Doctors Without Borders

2010 - Member, American Association for the Study of Liver Disease (Appointee to the Hepatobiliary Neoplasia Membership & Mentorship Subcommittee)

2012 - Member, American Gastroenterological Association

2016 - Member, American Association for the Advancement of Science

2017 - Member, International Liver Cancer Association

Honors

2000 Merit-based scholarship, Northwestern University

2000 Graduation with B.A. Summa Cum Laude, Northwestern University

2005 Finalist, Fulbright Fellowship to Spain

2007 Ruth L. Kirschstein National Research Service Award, National Institutes of Health

2007 Jacob Kaplan Award for Gastroenterology Research, Minnesota Medical Foundation

2007 Jan Lunden Award for Molecular Hepatology Research, Minnesota Medical Foundation

2009 Graduating Medical Student Research Award, Minnesota Medical Foundation

2014 Award Winner, 52nd Annual Komarov Research Competition, Philadelphia Gastroenterology Research Forum

2015 Frank Brooks Research Award for Gastroenterology Fellows, University of Pennsylvania

2017 Junior Investigator Award, International Liver Cancer Association

2017 Finalist, Career Awards for Medical Scientists, Burroughs-Wellcome Fund

2017 Holmes Award for Best Early Career Faculty Abstract, Department of Medicine, University of Pennsylvania

2018 Young Physician-Scientist Award, The American Society for Clinical Investigation

2018 Selected for an oral presentation, AASLD/EASL Masterclass

C. Contribution to Science

1. *Regenerative Biology and Cancer*: There is a shortage of liver organs for transplantation, and stem cell-derived hepatocytes may provide an alternative to liver organ transplantation. To better understand how the liver recovers from injury – and to identify targets for treatment of liver injury – I examined the gene expression pattern of repopulating hepatocytes to discover a crucial role for redox signaling in driving recovery from liver injury. I have investigated how hepatocytes can reverse senescence to undergo continuous proliferation after transplantation to the injured liver. I have also determined that hepatocytes, not hepatic progenitor cells, are the cell of origin of HCC, by performing genetic lineage tracing. Finally, I investigated stem cell signaling in the gut, and helped find a novel and critical cell type that surrounds the gut crypts, termed the telocyte.

    a. Wang AW*, **Wangensteen KJ***, Wang YJ, Zahm AM, Moss NG, Erez N, Kaestner KH. TRAP-seq identifies cystine/glutamate antiporter as a driver of recovery from liver injury. J Clin Invest. 2018 Jun 1;128(6):2297-2309. PubMed PMID: 29517978; PubMed Central PMCID: PMC5983312. *co-first authors.

    b. Shoshkes-Carmel M, Wang YJ, **Wangensteen KJ**, Tóth B, Kondo A, Massasa EE, Itzkovitz S, Kaestner KH. Subepithelial telocytes are an important source of Wnts that supports intestinal crypts. Nature. 2018 May;557(7704):242-246. PubMed PMID: 29720649; PubMed Central PMCID: PMC5966331.

c. Shin S*, **Wangensteen KJ***, Teta-Bissett M*, Wang YJ, Mosleh-Shirazi E, Buza EL, Greenbaum LE, Kaestner KH. Genetic lineage tracing analysis of the cell of origin of hepatotoxin-induced liver tumors in mice. Hepatology. 2016 Oct;64(4):1163-1177. PubMed PMID: 27099001; PubMed Central PMCID: PMC5033674. *co-first authors.
d. Wang MJ, Chen F, Li JX, Liu CC, Zhang HB, Xia Y, Yu B, You P, Xiang D, Lu L, Yao H, Borjigin U, Yang GS, **Wangensteen KJ**, He ZY, Wang X, Hu YP. Reversal of hepatocyte senescence after continuous in vivo cell proliferation. Hepatology. 2014 Jul;60(1):349-61. PubMed PMID: 24711261.

2. *Transposon biology*: Whole genome sequencing of organisms including zebrafish, mouse and humans has led to a wealth of information about gene sequences, and has revolutionized approaches to understand disease biology. I have been involved with a number of projects using DNA transposons to characterize gene function through screening, overexpression, and gene deletion techniques. I helped to develop the *Sleeping Beauty* and *Tol2* transposon systems for *in vivo* genetic screens in the zebrafish, and for gene transfer in human cell lines and in mice, including for germline gene transfer and for liver gene therapy.

a. Ni J, **Wangensteen KJ**, Nelsen D, Balciunas D, Skuster KJ, Urban MD, Ekker SC. Active recombinant Tol2 transposase for gene transfer and gene discovery applications. Mob DNA. 2016;7:6. PubMed PMID: 27042235; PubMed Central PMCID: PMC4818426.
b. Keng VW, Ryan BJ, **Wangensteen KJ**, Balciunas D, Schmedt C, Ekker SC, Largaespada DA. Efficient transposition of Tol2 in the mouse germline. Genetics. 2009 Dec;183(4):1565-73. PubMed PMID: 19805821; PubMed Central PMCID: PMC2787440.
c. Wilber A*, **Wangensteen KJ***, Chen Y, Zhuo L, Frandsen JL, Bell JB, Chen ZJ, Ekker SC, McIvor RS, Wang X. Messenger RNA as a source of transposase for sleeping beauty transposon-mediated correction of hereditary tyrosinemia type I. Mol Ther. 2007 Jul;15(7):1280-7. PubMed PMID: 17440442. *co-first authors.
d. Balciunas D, **Wangensteen KJ**, Wilber A, Bell J, Geurts A, Sivasubbu S, Wang X, Hackett PB, Largaespada DA, McIvor RS, Ekker SC. Harnessing a high cargo-capacity transposon for genetic applications in vertebrates. PLoS Genet. 2006 Nov 10;2(11):e169. PubMed PMID: 17096595; PubMed Central PMCID: PMC1635535.

3. *Clinical Gastroenterology*: I have focused on gastrointestinal diseases. I published a review on hepatitis C screening, treatment, and outcomes, including a discussion on the importance of screening for hepatocellular carcinoma. I also reported on unusual cases encountered in the clinic. One example was a case study and review of rare cases of massive hemorrhoidal bleeding after prostate biopsy. I published a case series of parkinsonism in patients treated for hepatitis C using interferon, includes a review of the literature on the possible association between interferons and Parkinson's disease. I also published a report of the first case of pre-surgical diagnosis of myointimal hyperplasia of the mesenteric veins, a rare disease of the gut vasculature. Diagnosis prior to surgical intervention led to a safe approach and a good outcome for the patient. I participated in a retrospective study investigating the clinical outcomes of patients with autoimmune hepatitis and coincident nonalcoholic steatohepatitis.

a. Mahmud N, **Wangensteen KJ**. Endoscopic Band Ligation to Treat a Massive Hemorrhoidal Hemorrhage Following a Transrectal Ultrasound-Guided Prostate Biopsy. Ann Coloproctol. 2018 Feb;34(1):47-51. PubMed PMID: 29535988; PubMed Central PMCID: PMC5847404.
b. De Luca-Johnson J, **Wangensteen KJ**, Hanson J, Krawitt E, Wilcox R. Natural History of Patients Presenting with Autoimmune Hepatitis and Coincident Nonalcoholic Fatty Liver Disease. Dig Dis Sci. 2016 Sep;61(9):2710-20. PubMed PMID: 27262844.
c. **Wangensteen KJ**, Krawitt EL, Hamill RW, Boyd JT. Parkinsonism in Patients With Chronic Hepatitis C Treated With Interferons: Case Reports and Review of the Literature. Clin Neuropharmacol. 2016 Jan-Feb;39(1):1-5. PubMed PMID: 26757310.
d. **Wangensteen KJ**, Fogt F, Kann BR, Osterman MT. Idiopathic Myointimal Hyperplasia of the Mesenteric Veins Diagnosed Preoperatively. J Clin Gastroenterol. 2015 Jul;49(6):491-4. PubMed PMID: 25626629.

Complete List of Published Work in My Bibliography:
https://www.ncbi.nlm.nih.gov/myncbi/kirk.wangensteen.1/bibliography/40417448/public/

D. Additional Information: Research Support and/or Scholastic Performance

Ongoing Research Support

K08 DK106478-01 Wangensteen (PI) 07/15/15-04/30/20
NIH/NIDDK
Genetic basis of liver repopulation
The hypothesis we test in this proposal is that Foxa3 and TNFR1 play critical roles in regulating liver regeneration. We propose the following Aims: (1) To investigate the mechanisms underlying Foxa3-mediated promotion of liver repopulation. (2) To assess whether TNFR1 deletion and targeted anti-TNF therapy can promote liver repopulation.
Role: PI

McCabe Fund Award Wangensteen (PI) 07/01/18-06/30/19
The Thomas B. McCabe and Jeannette E. Laws McCabe Fund
Elucidating mechanisms and treatments for liver cancer through a novel in vivo CRISPR screening platform
The overarching goal of this proposal is to discover new targets and treatments in HCC using an innovative in vivo genetic screening platform. Aim 1 is to identify target genes that are sufficient and necessary for HCC and Aim 2 is to develop novel drugs for HCC in vivo.
Role: PI

TAPITMAT Wangensteen (PI) 02/01/19-01/31/21
The Institute for Translational Medicine and Therapeutics (ITMAT)
Strategy to safely repopulate the uninjured host liver with engineered hepatocytes
To identify factors capable of driving liver repopulation in uninjured liver by performing an unbiased *in vivo* CRISPRa screen for novel genes or combinations of genes that promote tumor-free hepatocyte engraftment and proliferation.
Role: MPI

Sub of P30-DK050306 Wangensteen (PI) 07/01/15-06/30/16
NIH/NIDDK
Germline genetics of liver cancer
To determine the prevalence of germline mutations in patients with current or previous diagnosis of HCC, and to uncover whether subgroups are at higher risk, such as patients with a family history of cancers.
Role: PI

5T32DK007066 Wang (PI) 09/01/17-08/31/20
NIH/NIDDK
Elucidating Redox Regulation In The Repopulating Liver
This study will address The question of whether replicating hepatocytes have higher or lower redox states relative to quiescent hepatocytes. In addition, I will perturb The level of expression of Slc7a11 and to assess The effect on The liver's Redox state. This study will provide an in-depth understanding of temporal and regional specificity of redox regulation during Liver repopulation and will identify novel potential targets that might be employed for the treatment of acute Liver *Injury* by inducing *Hepatocyte* replication.
Role: Co-mentor

Completed Research Support

Pilot Grant Wangensteen (PI) 07/01/16-06/30/17
American Gastroenterological Association
Massively parallel CRISPRa screen to discover drivers of liver repopulation
We hypothesize our screen will uncover the most important genetic pathways driving liver repopulation, and will allow us to identify novel drug targets. Furthermore, our first-ever in vivo CRISPRa system will be a valuable resource for the biomedical community including the AGA.
Role: PI

Sub of P30-DK050306 Wangensteen (PI) 07/01/15-06/30/16
NIH/NIDDK
Elucidation of the genetic profile of repopulating hepatocytes

Prior research on hepatocyte proliferation has focused on the easily accessible paradigm of partial hepatectomy, which does not model the regenerative response of hepatocytes following toxic injury, such as occurs following alcohol or acetaminophen poisoning or acute viral hepatitis. To address this knowledge gap, we propose to utilize an innovative model system to identify the genes that control hepatocyte proliferation in the context of toxic liver damage.
Role: PI

Nominations to Prevention Peer Review Panels

- Jasjit Singh Ahluwalia
- Deanna G.K. Teoh, M.D.

Jasjit S. Ahluwalia, MD, MPH, MS
Professor, Behavioral and Social Sciences, Brown University School of Public Health
and Center for Alcohol and Addiction Studies
Professor, Medicine, Brown University Alpert Medical School

Dr. Ahluwalia is a physician and population health/public health scientist. He has been in academic medicine since 1992 and has been a practicing physician, faculty member, department chair, Associate Dean and Center Director in medical schools, and recently, served as a School of Public Health Dean. His primary research has focused on nicotine addiction and smoking cessation in African-American smokers by way of conducting clinical trials, secondary analysis, qualitative research, and clinical epidemiology research. Ahluwalia then extended his research through national collaborations to the role of menthol in quitting, pharmacokinetics of nicotine, pharmacogenetics, and cancer biomarkers. Another stream of research is broadly in the area of health disparities, racism, and minority health. Finally, he is engaged in global efforts with research projects in Mumbai (funded by Fogarty) and New Delhi, India.

He has received more than $21 million in funding as principal investigator and more than $80 million as co-investigator and has published more than 300 manuscripts. Additionally, Ahluwalia served as the inaugural chair of a charted NIH study section titled, Health Disparities and Equity Promotion, and in 2014, completed a 3-year term on the federal government's NIH/DHHS National Advisory Council on Minority Health and Health Disparities, for which he served as chair during the last year of his term.

Among other honors, Ahluwalia received the Society of Behavioral Medicine's national award for his excellence in mentoring, the Herbert W. Nickens award from the Society of General Internal Medicine for national leadership and research in improving minority health, and a lifetime leadership award from the American Public Health Association for his work on tobacco. He has been a member of the boards of directors of the Society of Behavioral Medicine, the Society of General Internal Medicine, the Association for Clinical and Translational Science, and currently serves on the board for the Society for Research on Nicotine and Tobacco.

Ahluwalia received his undergraduate degree at New York University and a combined MD/MPH from the Tulane University Schools of Medicine and Public Health and Tropical Medicine. During a two-year fellowship at Harvard, he studied clinical epidemiology, trained in clinical research, and earned an MS in health policy from its T.H. Chan School of Public Health.

In 1992, Ahluwalia joined Emory University School of Medicine and Rollins School of Public Health as an assistant professor of medicine and health policy. He was named vice chair and director of research for the Department of Preventive Medicine and Public Health at the University of Kansas Medical Center in 1997 and then department chair in 2001, becoming the Sosland Family Endowed Chair in 2003. The department went from no extramural research funding to a nationally recognized department during his tenure.

In 2005, he relocated to University of Minnesota to establish the Office of Clinical Research, to increase the stature of clinical and translational research across the six health science schools; Medicine, Public Health, Pharmacy, Veterinary Medicine, Nursing and Dentistry. The office evolved into the NIH funded University of Minnesota Clinical and Translational Sciences Institute (funded by a NIH $55 million grant), for which he served as Associate Director leading clinical research training and career development for undergraduates, graduate students, fellows and junior faculty. In 2009, he was awarded a $6 million NIH center grant which led to the establishment of the Center for Health Equity. In 2015, he moved to the New York metro area and became Dean of the Rutgers School of Public Health. In September 2017, he joined Brown University School of Public Health as a tenured Professor and will focus on research, mentoring, and teaching graduate and undergraduate students.

Dr. Ahluwalia's strength and track record lies in building and growing programs, mentoring, leveraging through collaboration, inspiring others to work in teams, a passion for excellence, strong leadership skills, proven administrative experience of increasing authority, strategic planning, executing transformational culture change, and the ability to create an atmosphere that nurtures, values, and celebrates diversity.

Curriculum Vitae

Name: Jasjit Singh Ahluwalia, MD, MPH, MS

Address and Telephone:
Mailing address:
Brown University School of Public Health
Box G-S121-5 Providence, RI 02912

Office Location, FedEx, and UPS:
121 South Main Street, #505 Providence, RI 02903

office: 401-863-6654
email: jasjit_ahluwalia@brown.edu

Current Position:

September 2017 - present	Professor (tenured), Department of Behavioral and Social Sciences and Center for Alcohol and Addiction Studies, Brown University School of Public Health. Professor, Department of Medicine, Brown University Alpert School of Medicine
October 2016 – present	Adjunct Professor, Public Health Foundation of India (PHFI), New Delhi, India

Education/Training:

Council of Medical School Dean's Fellow, American Association for Medical Colleges (AAMC); July 1, 2004 - June 30, 2005

Harvard Medical School and The New England Deaconess Hospital General Internal Medicine Faculty Development and Fellowship Program two year fellowship, July 1990-June 1992.

Harvard School of Public Health, part-time for SM (Masters of Science), Department of Health Policy and Management, July 1990-June 1992.

University of North Carolina School of Medicine at Chapel Hill - UNC Hospital Internal Medicine Residency Program, June 1987 - June 1990

Tulane University School of Medicine. Degree and Date: M.D. June 1987

Tulane University School of Public Health and Tropical Medicine. Combined 4-Year M.D./M.P.H. Program. Degree and Date: M.P.H. June 1987 Graduation Honor - Outstanding Student Leadership Award, 1987

New York University - College of Arts and Sciences. Degree and Date: B.A. June 1983 Major: Biochemistry Minor: Philosophy; Phi Beta Kappa and Cum Laude.

Past Research/Employment and Faculty Appointments:

Independent Academic Consulting

June 2016 – August 2017 Providing research strategy and services at health sciences centers.

Rutgers University

May 2015 – May 2016 Professor, Department Epidemiology
Adjunct Professor, Department of Medicine, Robert Wood Johnson Medical School.
Member: Cancer Institute of New Jersey and the Center for Environmental Exposures and Disease

May 2015 – March 2016; Dean, Rutgers School of Public Health

‘

University of Minnesota

September 2005 - April 2015; Professor, Department of Internal Medicine, University of Minnesota Medical School and Adjunct Professor, Epidemiology and Community Health, School of Public Health. Member: UMN Cancer Center; Center for Women's Health; Faculty, Graduate School

July 1, 2009 - April 2015; Director, Center for Health Equity: An NIH Center of Excellence in Minority Health and Health Disparities

January 2011 - April 2015; Associate Director, Clinical and Translational Sciences Institute
Director, Clinical Research Training, Education and Career Development

September 2005 – August 2009 Associate Dean, Clinical Research, Medical School

Sept, 2005 - April 2008 Executive Director, Office of Clinical Research,
University of Minnesota Academic Health Center

University of Kansas

July 1, 2001 - August 2005; Chair and Sosland Family Professor (Promoted 7/1/02 and endowed Chair 4/1/03), Department of Preventive Medicine and Public Health. Joint appointments as Professor, Division of General Medicine, Department of Medicine; Department of Pediatrics; and, Department of Family Medicine at the University of Kansas School of Medicine

October, 2000 - August 2005; Director, Cancer Prevention, Control, and Population Sciences. Kansas Cancer Institute, University of Kansas Medical Center

July 2004 - August 2005; Director, MS degree in Clinical Research (Biostatistics, Epidemiology, and Medical tracks)

July 1, 1997 - June 30, 2001; Vice-Chair (directing the larger Kansas City campus), Director of Research, and Associate Professor, Department of Preventive Medicine. Joint appointments as Associate Professor, Division of General Medicine, Department of Medicine; Department of Pediatrics; and, Department of Family Medicine at the University of Kansas School of Medicine.

September 1, 1999 – June 2001; Director, Primary Care Fellowship. KU School of Medicine.

July 1997 – June 2001; Attending Physician outpatient General Medicine Clinic

Emory University

September 1992 - June 1997 at Emory University:
Assistant Professor, Division of General Internal Medicine, Department of Medicine at Emory University School of Medicine and Assistant Professor, Department of Health Policy and Management, Rollins School of Public Health
Attending Physician at Grady Memorial Hospital.
January 1995 - June 1997; Director, The Center for Smoking Cessation and Tobacco Control.
January 1995 - June 1997; Affiliate Faculty Member, Winship Cancer Center at Emory University.
July 1994 - June 1997; Assistant Medical Director, Urgent Care Center at Grady Hospital.
November 1992 - June 1994; Medical Director, Walk-In Clinic at Grady Memorial Hospital.

July 1990 - June 1992; Clinical Fellow in General Internal Medicine at the New England Deaconess Hospital and Research Fellow at Harvard Medical School.

July 1990 - June 1992; Fellow in General Internal Medicine at the Veterans Administration Medical Center, Manchester, N.H. (March 1991; Attending on the In-Patient Medical Service)

June 1987 - June 1990; Three Year Internal Medicine Residency at the University of North Carolina Hospitals at Chapel Hill.

June 1984 - August 1984; Research at Tulane University School of Medicine; Dept. of Physiology - Neurosciences Section, under Dr. F. Edward Dudek.

May 1983 - August 1983 and May 1981 - August 1981; Research Assistant at New York University School of Medicine, Department of Ophthalmology, under Dr. Paul Witkovsky.

June 1982 - August 1982; Dreyfuss Undergraduate Research Scholar at The University of Chicago, Department of Chemistry, under Dr. Jack Halpern.

Selected Continuing Education Experiences/Postgraduate Training:

Leadership and Human Resources Workshops –	
Motivating and Developing Staff	July 7, 2009
Understanding Change	July 21, 2009

Council of Medical School Dean's Fellow, AAMC; July 1, 2004 – June 30, 2005

AAMC - Executive Development Seminar for Associate Deans and Department Chairs. Lago Mar, FL; October 8-13, 2004.

Advanced Motivational Interviewing Albequerque, NM; August 24-25, 2002.

Center for Creative Leadership – Leadership Development Program. Colorado Springs, CO; July 15-19, 2002.

Motivational Interviewing and Brief Counseling Techniques: Training for Trainers. Drs William Miller and Stephen Rollnick, San Anton, Malta; October 13 -15, 1997

Licensure/Certification:

American Board of Internal Medicine Diplomat #134913; 1991 (Expired 2001)
Minnesota Medical License #48554; July 1, 2006 - Active
Kansas License #04-27304; December 6, 1997 (Expired 6/30/06; Inactive 2006; Expired 7/1/07)
Missouri License #MD115976; July 1, 1998 (Expired 1/31/06; Inactive 2006)
Georgia License #36081; October 8, 1992 (Inactive 1998)
Massachusetts #0432221; May 16, 1990 (Expired 1993)
North Carolina #32976; October 15, 1988 (Expired 1991)
Louisiana #19291; August 10,1987 (Expired 1988)
Federal Licensing Examination (FLEX); 1987
Medical Education #02101870050

Major Leadership Professional Associations:

Board of Directors, Society of Nicotine and Tobacco Research (SRNT); March 2016 – March 2019.
Board of Directors, Association of Clinical and Translational Sciences (ACTS); March 2013 - February 2017
Member (then Chair), National Advisory Council on Minority Health and Health Disparities of the National Institutes of Health; February 1, 2011 - February 28, 2015
Board of Directors, ACRT (Association of Clinical Research Training); April 2009 – March 2013
Member, Board of Directors, Association of Prevention Teaching and Research (APTR); March 2012 – February 2016
Member, Board of Directors for the Health Partners Research Foundation (Research arm of the nonprofit Health Partners Corporation; Minneapolis, MN); March 2006 - February 2009
Member Board of Directors (Member Delegate, Society of Behavioral Medicine (SBM); April 2005 - April 2008
Member Board of Directors (Council Member), Society of General Internal Medicine; May 2005 - April 2008

Honors, Awards, Offices, and Volunteer:

Brown University
Fellow, Society of Nicotine and Tobacco Research (SRNT); February 2018

University of Minnesota Academic Health Center
2014 APTR (Association for Prevention Teaching and Research) Duncan Clark Award for a distinguished record of achievement in the areas of teaching, research, and advocacy in the field of prevention and public health. Presented March 21, 2014 in Washington DC
2012 Prevent Cancer Foundation - Prevention Laurel for National Leadership; presented March 22, 2012 in Washington DC
2011 APHA (ATOD Section) Lifetime Achievement Award for tobacco research having an impact on improving the health of the public; November 2011
2010 ASPO (American Society for Preventive Oncology) Joe Cullen Award - to one whose leadership is exemplified by a commitment to fostering collaboration among the wide network of basic and behavioral research scientists, health care professionals and public health advocates in the fight against tobacco and tobacco-related disease; March 23, 2010
2009 SGIM Herbert W. Nickens Award for work in diversity in medicine and improving the health of minority populations; May 16, 2009

Mentor, President's Distinguished Faculty Mentor Program; 2006 - 2008

University of Kansas School of Medicine

F. Marian Bishop Educator of the Year award, Association of Teachers of Preventive Medicine (ATPM) presented in Albuquerque, New Mexico; March 2003

Member, Board of Directors for the University of Kansas Medical Center Research Institute (Nonprofit entity to manage all nonfederal grants); September 2002 – August 2003

Recipient, Annual Kemper Foundation Teaching Excellence Award (the University of Kansas' highest teaching award with a $5,000 stipend); August 2002.

Recipient, on behalf of the University of Kansas School of Medicine, Department of Preventive Medicine, the ATPM Outstanding Educational Program of the Year Award (recognizes an innovative program, department or academic institution for advancing undergraduate or graduate medical education in preventive medicine and public health); April 2001

Annual Mentor Role Model award, National Role Models Conference; September 2001

2001 Inaugural Society of Behavioral Medicine Annual Mentor of the Year Award. Presented in Washington DC; March 2001

2000 Annual University of Kansas Medical Center Researcher of the Year Investigator Award; November, 2000

2000 Pearl Maker Award from the Biomedical Synergistics Education Institute

Recipient, University of Kansas Medical School Class of 2002, Student Voice Teaching Award; April, 2000

Fellow, The Society of Behavioral Medicine (SBM); April 2000

Associate Director, W. Clarke Wescoe Academic Student Society; July 1999 -

Member, Board of the Association of Teachers of Preventive Medicine Foundation (ATPMF); March 1997 - February 2000

Recipient, Travel Award from the National Academy of Sciences to present a paper at the International Cancer Congress in Rio de Janeiro, Brazil; 1998

Robert Wood Johnson Foundation Generalist Physicians Faculty Scholar; July 1997 - June 2001

Emory University School of Medicine and School of Public Health

American Medical Association Young Physician Section National Community Service Award; June 1997

Awarded Fellowship in the International Society on Hypertension in Blacks (ISHIB); 1997

Nominee - Best Attending Award, Department of Medicine; 1995 - 1996

American Cancer Society Cancer Control Career Development Award;July 1, 1996 - June 30, 1999 relinquished after leaving Emory University and joining University of Kansas

Fellow, The American College of Preventive Medicine (FACPM); November, 1995

1995 Join Together National Leadership Fellowship Award; July 1, 1995 - June 30, 1996

Fellow, The American College of Physicians (FACP); January, 1995

Top 5% Award for Small Sessions Workshop titled *How To Help Your Patients Stop Smoking*; at the Annual Society of General Internal Medicine Meeting; 1994

Award for Best Abstract at Southern Section Society of General Internal Medicine annual meeting for abstract titled *Decline In The Use Of Brand Name NSAIDs After The Institution Of A Restriction Policy*; 1994

President's Commission on the Status of Minorities Award (Emory University); 1992, 93, 94

Harvard Medical School and The New England Deaconess Hospital

AMA/Burroughs Wellcome Co. Leadership Program Award; 1992

National Third Prize Winner - The American Journal of Preventive Medicine and The Ulrich and Ruth Frank Foundation for International Health for paper: "Housestaff Knowledge of Prevention Guidelines"; 1992

Regional Finalist, White House Fellowship Program; 1992
Preceptor in the Tulane University Career Externship Program for a visiting graduate student; January 6 - 10, 1992
Listed in Who's Who Among Rising Young Americans; 1992
Listed in Two Thousand Notable American Men; 1992
Medical Volunteer for Bridge Over Troubled Waters for Homeless and Disadvantaged Youth; July 1991 - June 1992
Attended George Washington University Summer Health Policy Institute; June 24 - 28, 1991
Selected for the AMA Summer Campaign Management School; July 14 - 19, 1991

University of North Carolina Hospitals at Chapel Hill
Member on the Hospital Bioethics Committee; 1989 - 1990

Tulane University School of Medicine and School of Public Health
President of 1st Year Medical School Class of '87; 1983 - 84
Tulane School of Public Health Outstanding Student Leadership Award (graduation); 1987
Joseph Collins Foundation Scholarship; 1986
Commissioned Officer Student Extern Program (COSTEP); at the National Institute of Mental Health - Public Health Service - United States DHHS. Nov. 1986 – Dec. 1986
Scholarship Award to participate in the Summer Institute in Geriatrics at Boston University Medical Center sponsored by the National Institute of Aging and the American Geriatric Society; 1986
American Medical Association - Medical Student Section (AMA-MSS) Tulane Delegate to the National and Interim Conventions; 1985-87
Joseph Goldberger Scholarship in the Clinical Nutrition Program at the Baylor College of Medicine sponsored by the American Medical Association - Education and Research Foundation;1986
National First Prize Winner - Olive W. Garvey Center for paper titled: "Basic Biomedical Ethics and Its Application to the Treatment of Newborns With Birth Defects"; 1985
Finalist Award - American College National Scholarship; 1985, 1986
Vice President Phi Delta Epsilon Medical Fraternity; 1985
Co-Chairman of the Committee on Premedical Students of the Student Advisory Board; 1984-85
First Prize - American College National Scholarship; 1984
Recipient Short Term Research Grant sponsored by the National Institute of Health and Office of the Dean of the School of Medicine; 1984
American Medical Student Association - Membership Coordinator; 1984-85, Freshman Representative; 1983-84
Member on Tulane Honor Board; 1983-84
Physicians for Social Responsibility - Tulane Chapter Treasurer; 1983-84

New York University
Phi Beta Kappa (awarded junior year); 1982
NYU University Scholar; 1979 - 1983
Caducean Society (Honorary Premedical Society); 1982
Pi Mu Epsilon (Honorary Mathematics Society); 1982
Varsity Letter - 4 years; Co-captain New York University Varsity Tennis; 1979 - 1983
Dreyfuss Summer Research Scholar at the University of Chicago; 1982
New York University Founder's Day Award; 1983
New York State Regents Scholarship; 1979 - 1983
Dean's List; 1979 – 1983

Professional Associations:

American Association for Cancer Research (#147876)
American College of Epidemiology (ACE)
American Diabetes Association (ADA) – Member #000113605
Professional Section #042530640004972
American Diabetes Association (ADA) – Layperson #520551763
American Medical Association (AMA) #0210-1870-050
American Medical Informatics Association (AMIA) # 0000049348
American Federation for Clinical Research (AFCR)
American Federation for Medical Research (AMCR)
American College of Physicians (ACP) #00053577
American Heart Association's Council on Epidemiology and Prevention (#100001443959)
Academy for Health Services Research and Health Policy (# 10001)
American Public Health Association (APHA) #4522041
Association of Clinical Research Training (ACRT)
Association for Medical Education and Research in Substance Abuse (AMERSA)
Association for Patient-Oriented Research (APOR)
Association of Teachers of Preventive Medicine (ATPM)
American Association for Cancer Education (AACE)
American Society of Preventive Oncology (ASPO)
Global Health Council
International Society of Cancer Prevention (ISCaP)
National Hispanic Science Network on Drug Abuse (NHSN)
North American Association for the Study of Obesity (NAASO) #001127
Society for Behavioral Medicine (SBM)
Society for Epidemiologic Research (SER) #00SER-12573
Society of General Internal Medicine (SGIM)
Society for Public Health Education (SOPHE) #002308
Society for Research on Nicotine and Tobacco (SRNT) #1020
Europe Chapter - Society for Research on Nicotine and Tobacco (SRNT) #1020

Study Sections:

NIH, Member, Planning Grants for Global Research Infrastructure in Non-Communicable Disease (ad hoc); April 27-28, 2016
Chair (Founding), Health Disparities and Equity Promotion Study Section (2010/10 ZRG1 HDEP-D (01) S), National Institutes of Health, CSR; June 2010 - 2011
National Center for Research Resources, NIH, Member, Special Emphasis Panel for Clinical Research Curriculum Award (K30) Reviews (ZRR1 CR-1); September 24-25, 2009.
National Cancer Institute, NIH, Member, Special Emphasis Panel for P01 Reviews (ZCA1 RPRB-7-01); June 16-17, 2009.
Minnesota Partnership for Action Against Tobacco (MPAAT) Chair, Review Panel on Community and Academic Partnership research awards; February 2004
Minnesota Partnership for Action Against Tobacco (MPAAT) Member, Review Panel on Tobacco Treatment Centers; August 2003
Centers for Disease Control (National Center for Chronic Disease Prevention and Health Promotion) Special Emphasis Panel on Prevention Research Centers; July 2003

National Cancer Institute, NIH, Member, Special Emphasis Panel for the 2003 Loan Repayment Program (ZCA1 SRRB-Y); May 2003.
University of Kansas Medical Center Research Institute. Member Regional Peer Review Panel to review Clinical Pilot, Basic Science, and Mentored Clinician Scientist grant proposals.
National Institutes of Health, Center for Scientific Review. Ad-hoc member, Social Sciences, Nursing, Epidemiology and Methods (SNEM-1) Integrated Review Group. March 2001
Centers for Disease Control (National Center for Chronic Disease Prevention and Health Promotion) Special Emphasis Panel on Prevention Research Center Special Interest Projects; June 1999
The Robert Wood Johnson Foundation Initiative on Translating Science to Practice: Building An Action Strategy Into Transdisciplinary Tobacco Use. Reviewer; May 2000
State of California, Tobacco-Related Disease Research Program's Academic and Community Partnership Study Section Reviewer; May 1999
The Robert Wood Johnson Foundation Initiative on Addressing Tobacco in Managed Care. Member, Review Panel and National Advisory Committee; January 1998 – Dec 2003
National Cancer Institute, NIH, Member, Special Emphasis Panel for RFA CA98-002 "Prevention and Cessation of Tobacco Use by Children and Youth in the U.S;" June 1998
State of California, Tobacco-Related Disease Research Program's Integrated Research Projects Study Section Reviewer; November 1997
Susan G. Komen Breast Cancer Foundation Clinical and Translational Research Study Section Reviewer; 1997
State of California, Tobacco-Related Disease Research Program's Sociobehavioral Study Section Reviewer; May 1997

Editor Positions and Editorial Boards:

Editorial Board Member, *Journal of General Internal Medicine*; May 2011 - April 2014
Editorial Board Member, Addiction Science and Clinical Practice; May 2011 - 2016
Editorial Board Member, *American Journal of Preventive Medicine*; Jan. 2004 - 2012
Deputy Editor, *Journal of General Internal Medicine*; July 2004 - June 2007
Editorial Review Board, supplement to the *Annals of Behavioral Medicine* for the Behavior Change Consortium (BCC) and the National Institutes of Health; 2004
Associate/Action Editor, *Nicotine and Tobacco Research*; February 2000 - 2002
Associate Editor for Research, SGIM Forum Newsletter; July 1999 - June 2000
Faculty Editorial Advisory Board. *Journal for Minority Medical Students*; January 1999 - 2001

Reviewer:

Reviewer, *Annals of Internal Medicine,* 1998 –
Reviewer, *Journal of the American Medical Association,* 1997 -
Reviewer, *Archives of Internal Medicine,* 1996 -
Reviewer, *American Journal of Public Health,* 1995 –
Reviewer, *Nicotine and Tobacco Research*; 2000 -
Reviewer, *Journal of General Internal Medicine,* 1995 -
Reviewer, *Preventive Medicine*; 1995 –
Reviewer, *ACP Journal Club* (*Annals of Internal Medicine*); 1994 – 1998
Reviewer, *American Journal of Medicine,* 2002 – 2004
Reviewer, *Ethnicity and Disease,* 1998 – 2003
Reviewer, *Medical Care,* 1998 - 2005

Reviewer, *Tobacco Control: An International Journal*, 1995 - 1997
Scientific Reviewer, Surgeon General's Report, *Tobacco Use in Minorities*, 1996
Scientific Reviewer, Treating Tobacco Use and Dependence: A Clinical Practice Guideline, 2000

Visiting Professor:

California State University San Marcos. September 14-15, 2017
Medical University of South Carolina, Hollings Cancer Center. September 9, 2016
University of Texas Health Science Center at San Antonio, Frederic C. Bartter Visiting Professor. November 10-12, 2014
University of Arizona Health Sciences Center, Office of the Senior Vice President for Health Sciences. May 7-8, 2014
University of Illinois, Chicago, Cancer Center's Populations Sciences Program and NCI R25 Program. May 5-6, 2010
Distinguished Visiting Scholar, Department of Preventive Medicine, University of Kansas School of Medicine. August 16-18, 2009
K12 and K30 Clinical Research Programs at University of North Carolina School of Medicine. August 18, 2006
Cancer Prevention, Control, and Populations Sciences Program, Memorial Sloan Kettering Cancer Center. May 7, 2006
K12 and K30 Clinical Research Programs at Baylor College of Medicine. February 15, 2006
Health Promotion and Disease Prevention Visiting Professor at the Medical College of Georgia. January 27-28, 1998.

Board of Directors and Scientific Advisory Boards:

Member, Technical Advisory Committee, Public Health Research Institute (PHFI) – Implementing a Settings Based Health Promotion Intervention for Prevention and Control of Non-Communicable Diseases (NCDs). 2018 -
Member, International Advisory Board, ASTRA – Addressing Smokeless Tobacco Use and Building Research Capacity in South Asia (funded by the United Kingdom's National Institute of Health Research); July 2018 -
External Advisory Board, Memorial Sloan Kettering/CUNY NIH P20 program on Tobacco Health Disparities; 2015-2018
Chair, External Advisory Board, University of Arizona Health Sciences Center, PRIDE Training Program for Faculty Underrepresented in Biomedical Sciences (NHLBI R25 program); 2015 - 2018
Member, Leadership Advisory Board, Rutgers Institute for Food and Nutrition Advisory Board; 2015 - 2016
Member, Internal Advisory Board, Rutgers University Cancer Institute of New Jersey; September 2015 - 2016
Member, External Advisory Board, Georgetown-Howard CTSA Program in Education, Training, and Career Development; 2013-2015
Member, Steering Committee and Program Committee and Co-Chair Planning Committee for the US Department of Health and Human Services 2012 Summit on the Science of Eliminating Health Disparities; Washington, DC; Oct 31 – Nov 2, 2012
Board of Directors, Association of Clinical and Translational Sciences (ACTS); January 2013 – December 2015

Member, National Advisory Council on Minority Health and Health Disparities of the National Institutes of Health; February 1, 2011 - February 28, 2015
Board of Directors, ACRT (Association of Clinical Research Training); April 2009 – March 2013
Member, Scientific Advisory Board, National Institute of Mental Health (NIMH) African American Mental Health Research Scientist Consortium; May 2009 – April 2010
Member, External Advisory Committee, University of Illinois at Chicago, Cancer Education and Career Development Program (NCI R25 program); October 2009 – September 2012
Chair, Steering Committee, Minneapolis VA Medical Center, Center for Chronic Disease Outcomes Research (CCDOR), A VA Health Services Research Center of Excellence; January 2007 -
Member, Medical Advisory Board, Cancer Research and Prevention Foundation; September 2006 -
Board of Directors, HealthPartners Research Foundation; March 2006 - February 2009
Council Member (National Officer), Society of General Internal Medicine; May 2005 – April 2008
Delegate (National Officer), Society of Behavioral Medicine (SBM); April 2005 – March 2008
Member, Tobacco Consortium, Center for Child Health Research, American Academy of Pediatrics; January 2001 -
Member, Research Advisory Committee for the Minnesota Partnership for Action Against Tobacco; July 2000 – June 2004
Member, Scientific Advisory Panel for QuitNet Website (www.quitnet.org); April 2000 – Sept 2005
Member, Scientific Advisory Panel on Cessation, American Legacy Foundation; 2000 - 2004
Member, Board of Directors, Society for Research on Nicotine and Tobacco (SRNT); 1998
Ad-Hoc Advisory Member, NIH Transdisciplinary Tobacco Use Research Center (TTURCs); 1999
Member, National Advisory Committee. The Robert Wood Johnson Foundation's Initiative on Addressing Tobacco in Managed Care; January 1998 – December 2003

Pharmaceutical Scientific Advisory Boards:

Member, Nicotine Dependence National Advisory Board, Pfizer Pharmaceuticals; 2005-2008
Member, Multicultural National Advisory Board, GlaxoSmithKline; 2003-2004
Member, Prostate Disease National Advisory Board, GlaxoSmithKline; 2002-2003
Member, Nicotine Dependence National Advisory Board, Pharmacia Consumers; 2001-2002
Member, Nicotine Dependence National Advisory Board, GlaxoSmithKline; 1998-2001

Academic, Scientific Organization and Hospital Committees (National, Regional and Local):

Member, Committee on Public Health Faculty Appointments (P&T), Brown University School of Public Health; September 2018 -
Planning Committee, National Hispanic Science Network (NHSN) 2018 Annual Scientific Meeting
Member, Diversity and Inclusion Committee, Brown University School of Public Health; September 2017-2018
Faculty Advisor to Brown University Undergraduate Public Health Concentration students (~30 students); September 2017 -
Member, Brown University School of Public Health, Department of Behavioral and Social Sciences Predoctoral Admissions Committee; September 2017 -
Member, CAAS Postdoctoral Training Committee (NIDA T32 and NIAAA T32); September 2017 -
Member, Brown School of Public Health Diversity and Inclusion Planning Advisory Committee; November 2017 -
Member, Brown University School of Public Health Undergraduate Studies Committee; September 2017 -
Faculty Advisor to Public Health Concentration Departmental Undergraduate

Group (DUG); September 2017 -
Member, Planning Committee, 2015 Annual Translational Sciences Scientific Meeting Conference
Member, Award Subcommittee, Annual Translational Sciences 2014 Conference; April 9-11, 2014
Member, Planning Committee, 2014 Annual Translational Sciences Scientific Meeting Conference
Member, Planning Committee, 2013 National Hispanic Science Network (NHSN) Annual International Conference; October 9 – 11, 2013
Member, Planning Committee, 2013 Annual Translational Sciences Scientific Meeting Conference
Member, Steering Committee and Program Committee for the US Department of Health and Human Services 2012 Summit on the Science of Eliminating Health Disparities; 2012
Co-Chair, Society for Research on Nicotine and Tobacco (SRNT) Treatment Network, 2010 - 2013
Member, University of Minnesota, Young Investigator of the Year selection committee, 2011
Member, Steering Committee, University of Minnesota Hematology Research Training Program (T32); 2010 - 2012
Member, Exhibitor and Supporter Committee for the 2011 annual Clinical and Translational Research Meeting, Washington, DC; November 2010 – April 2011.
Member, Symposium Planning Committee, National Conference on Keeping Our Faculties of Color Symposium: Faculty Diversity in Higher Education; November 1-2, 2010
Moderator, 2010 ICBM (International Congress of Behavioral Medicine) annual meeting Paper Session *Theories and Applications in Behavioral Medicine*; August 5, 2010
Member, Interdisciplinary Advisory Committee for NIH BIRCWH K12 (Building Interdisciplinary Research Careers in Women's Health); July 2010 - 2015
Member, Executive Committee, University of Minnesota Surgical Oncology Training Program (5 T32 CA132715); 2010 - 2015
Reviewer, University of Minnesota and Indian Council for Medical Research Joint Pilot Grants Program for collaborative research; Spring 2010
Member, Award Selection Committee for the University of Minnesota Medical School's inaugural Young Investigator Award; Spring 2010
Member, Planning Committee for 2010 SRNT annual meeting Preconference Workshop *Cultural Tailoring of Smoking Cessation Interventions for Minority Racial/Ethnic and LGBT Populations*; February 23-27, 2010
Moderator and Panelist, 2010 SRNT annual meeting Preconference Workshop *Cultural Tailoring of Smoking Cessation Interventions for Minority Racial/Ethnic and LGBT Populations*; February 23, 2010
Member, Planning Committee for *Keeping Our Faculties V*, a national symposium devoted to helping colleges and universities attract, recruit, advance, and retain faculty of color (Conference: October 28-29, 2010)
Member, Tobacco Related Health Disparities workgroup, Society for Research on Nicotine and Tobacco. July 2009 - June 2010
Mentor (year long), National Institute of Mental Health (NIMH) African American Mental Health Research Scientist Consortium; May 2009 - April 2010
Member, Lung Cancer Research Program (LCRP) Stakeholders Mtg for the Congressionally Directed Medical Research Programs (CDMRP); February 2009
Chair and Facilitator, Robert Wood Johnson Foundation's Healthy Eating Research Initiative – New Connections Grantee and Mentor Workshop, St. Paul, MN; October 15, 2008
Member, Advisory Board for the Applied Clinical Research Program, Department of Medicine, University of Minnesota Medical School; July 2007 - 2015
Member, Ad hoc Committee to review Medical School Promotion and Tenure Criteria; 2007
Member, Steering Committee for the University of Minnesota and Indian Council for Medical Research (ICMR) Partnership; January 2007 - December 2008
Member, Medical School Dean's Task Force on Qualifications for Admissions; 2007

Member, International Medical Education and Research (IMER) Advisory Committee, University of Minnesota School of Medicine; July 1, 2006 -
Chair, Smoking in Minority Populations Paper Session; National Scientific Meeting for the Society of Behavioral Medicine in San Francisco, CA; March 2006
Member, IRB Consultative Committee of the Vice President for Research, University of Minnesota
Member, University of Minnesota Comprehensive Cancer Center; 2005 - 2015
Member, University of Minnesota Center for Women's Health; 2005 - 2015
Member, University of Minnesota Obesity Prevention Center Executive Committee; Sept 2005 -
Member, University of Minnesota (NIH K-12) Medical Advisory Committee; October 2005 – July 2008
Member, University of Minnesota GCRC Advisory Committee; September 2005 – April 2008
Member, University of Minnesota Presidential Transforming the University Task Force on Clinical Science Enterprise Strategic Positioning; Sept 2005 – June 2006
Council Member (National Officer), Society of General Internal Medicine; May 2005 – April 2008
Expert Consultant (Minority Health, Smoking, Obesity), annual scientific meeting of the Society of Behavioral Medicine; April 14, 2005
Chair, Body Image and Health Behaviors paper session, annual scientific meeting of the Society of Behavioral Medicine; April 14, 2005
Member Delegate (National Officer), Society of Behavioral Medicine (SBM); April 2005 – April 2008
Co-Chair, Alcohol/Smoking/Substance Abuse Track for the International Congress of Behavioral Medicine meeting in Bangkok, Thailand; November 28 - December 2, 2006.
Member, International Congress of Behavioral Medicine Program Committee for meeting in Bangkok, Thailand; November 28 - December 2, 2006.
Member, Society of General Internal Medicine (SGIM) Research Cluster Group; 2005 - 2008
Member, Scientific Advisory Board. Kansas Physicians Engaged in Primary Care Research (KPEPR) - a Practice Based Research Network; July 2001 – June 2005
Member (Ex Officio), University of Kansas Medical Center GAC (General Clinical Research Center Advisory Committee); 2004 - 2005
Member, University of Kansas School of Medicine Ad Hoc Compensation Committee; 2003
Member, Prevention Abstract Selection Committee for the 2003 Annual Meeting of the Society of General Internal Medicine (SGIM)
Member, Scope of Clinical Research Training Programs Task Force of the NIH K30 Training Program; 2003-2005
Associate Director, Kansas Physicians Engaged in Primary Care Research (KPEPR) - a Practice Based Research Network; July 2001 - June 2004
Member, Nominations Committee, Society of Behavioral Medicine (SBM); 2002-2005
Member, Board of Directors for the University of Kansas Medical Center Research Institute (Nonprofit entity to manage all nonfederal grants); September 2002 – June 2003
Member, University of Kansas Medical Center Clinical Research Advisory Committee; 2002 - 2004
Member, Selection Committee for the University of Kansas Chancellors Club Research Award; 2002-2003
Member, Advisory Committee on Preventive Health Services Collaborative. Bureau of Primary Health Care, HRSA in partnership with the Institute for Healthcare Improvement. June 2002
Member, Clinical Research Advisory Committee, University of Kansas Medical Center. July 2002-
Member, Steering and Planning Committee, Collaborative Conference on Women, Tobacco, and Cancer. National Cancer Institute, the Office of Women's Health (DHHS), the Office of Research on Women's Health, and the American Cancer Society. 2002
Panelist, Workshop titled Graduate Students Research in Behavioral Medicine: Thesis, Dissertation, and Beyond! Annual Society of Behavioral Medicine meeting. Washington, DC; 2002

One-on-One Mentor, annual Society of General Internal Medicine meeting (Mentee:Carmen Guerra, MD,MPH, Assistant Professor of Internal Medicine, University of Pennsylvania); 2002
Member, Selection Committee for the Annual Mentor of the Year Award, Society of Behavioral Medicine; 2002
Member, John Eisenberg 2002 Award Committee, Society for General Internal Medicine
Member, Professional and Scientific Liaison Council, Society of Behavioral Medicine; 2001 - 2002
Chair, Clinical Trials Scientific Session. 2001 Society for General Internal Medicine Annual Scientific Meeting. San Diego, CA
Chair, Faculty Search Committees for six tenure track faculty in the Department of Preventive Medicine; 1998-2001
Chair, Society for Research on Nicotine and Tobacco Annual Scientific Conference paper session titled Smoking Reduction Strategies: Lay Perceptions and Implications for Smoking Cessation; March 2001
Member, Grants Review Committee for Hall Foundation Sponsored University of Kansas Medical Center/Children's Mercy Hospital Grants Program; April 2001
Co-Chair, Patient Centered Abstract Selection Committee for the 2001 Annual Meeting of the Society of General Internal Medicine (SGIM)
Member, Review Committee for KUMC-MRI (Midwest Research Institute) Grants Program; 2000
Member, Review Committee for KU Shared Biomedical Research Equipment Funds; 2000 - 2003
Invited Presenter (one of twelve scientists), Decade of Behavior launch in Washington, D.C. Led by American Psychological Association and co-sponsored by 45 other organizations including NIH; September 26, 2000
Elected Member, University of Kansas School of Medicine Research Committee; September 2000 – August 2003
Member, Transition Team, Primary Care Physician's Initiative at KUMC.
A $15 million grant from the Kansas Health Foundation; 2000
Chair, Ethnicity and Addictive Diseases Paper Session, Society of Behavioral Medicine (SBM) Year 2000 Annual Scientific Meeting; April 2000.
Chair, Search Committee for the Director of General Internal Medicine and Geriatrics; January 2000
Invited Participant, Meeting on Methodology and Outcome Measures for Tobacco Use Cessation, Sponsored by NCI/NIDA/CDC/SRNT/RWJF; November 8 – 9, 1999
Member, Professional Assistance in Cessation Therapy Workgroup (PACT); October 1999 -
Member, Internal Advisory Board, Center on Aging, University of Kansas School of Medicine; July 1999 - 2003
Member, Tobacco Cessation Planning Subcommittee for the 11th World Conference on Tobacco OR Health, May 1999 – Aug 2000
Chair, Nominating Committee for the Board of the Society for Research on Nicotine and Tobacco (SRNT), 1999 - 2001.
Member, Internal Advisory Group for the Planning Grant for Multipurpose Clinical Research Center for Musculoskeletal Diseases; July 1999
Member, Society of Behavioral Medicine (SBM) Year 2000 Program Planning Committee and Chair Abstract Selection Subcommittee for Addictive Diseases; 1999
Member, Community of Color Tobacco Network
Member, Abstract Selection Committee for 1999 Annual Meeting of the Society of Research on Nicotine and Tobacco (SRNT)
Member, Steering Committee for the University of Kansas Center for Excellence in Minority Affairs; July 1998 – June 2001
Member, Minority Faculty Advisory Committee; July 1998 – June 2001
Member, Research Committee - Society of General Internal Medicine (SGIM); July 1999 – June 2002

Member, Health Policy Workshops Sub-Committee - 1999 National Meeting Program Planning Committee for Society of General Internal Medicine (SGIM).
Member, Substance Abuse Abstract Selection Committee for the 1999 Annual Meeting of the Society of Behavioral Medicine (SGIM)
Chair, KUMC Primary Care Physician Education Research Task Force; 1998
Member, Search Committee for the Chair, Department of Internal Medicine at the University of Kansas Medical Center; July 1998
Member, Search Committee for the Associate Dean for Cultural Enhancement and Diversity at the University of Kansas Medical Center; July 1998
Chair, Search Committee for the Director for newly created Center for Health Care Research at the University of Kansas Medical Center; May 1998
Member, Selection Committee for Associates Awards and Junior Faculty Awards for the 1998 Annual Meeting of the Society of General Internal Medicine (SGIM)
Member, Abstract Selection Committee for the 1998 Annual Meeting of the Society of General Internal Medicine (SGIM)
Member, Abstract Selection Committee for the 1998 13th Annual International Interdisciplinary Conference of the International Society on Hypertension in Blacks (ISHIB)
Member, Long Range Planning Committee, Society for Research on Nicotine and Tobacco (SRNT); 1997 - 2000
Member, Selections Committee - University of Kansas School of Medicine Primary Care Faculty Teaching Award; 1998
Member, Nominations Committee - Society of General Internal Medicine (SGIM) officers; 1998
Member, Physician Membership Committee, Society of Behavioral Medicine (SBM); 1997-1999
Member, Executive Operations Group, Primary Care Physician's Initiative at KUMC. A $15 million grant from the Kansas Health Foundation; 1997- 2000
Member, Abstract Selection Committee, Society for Research on Nicotine and Tobacco (SRNT) Annual Meeting; 1998
Member, Internal Advisory Committee of the Kansas Cancer Institute, University of Kansas Medical Center; July 1997 – June 2002
Member, Search Committee for Associate Dean of Research, University of Kansas Medical Center; 1997-1998
Member, Dean's Committee to Create Center for Health Care Research at University of Kansas Medical Center; July 1997 – June 1998
Invited Member, "Developing a Minority Health Services Research Agenda," sponsored by the American Association of American Colleges (AAMC) and the Agency for Health Care Policy and Research (AHCPR); July 17-18, 1997
Member, Program Planning Committee for Prevention '98: Science, Technology and Practice - annual meeting of the American College of Preventive Medicine; 1998
Member, Mid-Atlantic Conference Planning Committee for Partnership for Cancer Control in Underserved Populations. American Cancer Society and CDC, June 1997.
Director, Research Conference Series, Division of General Medicine, Emory University; September 1996 - June 1997
Member, Nominating Committee for the Board of the Society for Research on Nicotine and Tobacco (SRNT), 1997 - 1999.
Chair, Special Populations/Geriatrics Abstracts Sub-Committee - National Meeting Program Planning Committee for Society of General Internal Medicine (SGIM); 1997
SGIM Representative to the Cooperative Steering Committee of the Association of Teachers of Preventive Medicine (ATPM) and the Office of Disease Prevention and Health Promotion (ODPHP); 1996 - 1999.
Member, Abstract Selection Committee for Prevention '97 - Annual Meeting of the American College of Preventive Medicine; 1997

Member, Program Planning Committee for Prevention '97: Science, Technology and Practice - annual meeting of the American College of Preventive Medicine; 1997
Member, Oversite Committee, Grady Hospital Minority-Based Community Clinical Oncology Program; January 1996 - June 1996
Institutional Representative, Society of General Internal Medicine; May 1996 - June 1997
Member, Presidential Commission on the Status of Minorities, Emory University; 1995 – 1996 (and Co-Chair Faculty Committee) and 1996 - 1997.
Co-Chair, Workshops Section - National Meeting Program Planning Committee for Society of General Internal Medicine (SGIM); 1996
Member, Alcohol, Tobacco and Other Drugs (ATOD) Award selection committee for American Public Health Association (APHA); 1995
Member, Health and Public Policy Committee, American College of Physicians, Georgia Chapter; 1995 - 1996; 1996 - 1997.
Member, Health Services Research Abstract Selection Subcommittee for the Annual Meeting of the Society of General Internal Medicine (SGIM); 1995
Member, Emory University School of Medicine Minority Affairs Advisory Council; 1994 - 1995 and 1995 - 1996.
Chair, Exhibitors Section - National Meeting Program Planning Committee for Society of General Internal Medicine; 1995
Member, Abstract Selection Committee for the Annual Meeting of the Southern Society of General Internal Medicine (SSGIM); 1995
Member, Urgent Care Center Operations Committee, Grady Memorial Hospital; 1994 - 1996
Member, Behavioral and Prevention Working Group, Cancer Control Committee of the Winship Cancer Center, Emory University School of Medicine; 1993 - 1994.
Member, SGIM Health Policy Workshop Subcommittee for Annual Meeting; 1994
Member, Grady Memorial Hospital Emergency Care Center Committee; 1992 - 1993.
Member, Program Planning Committee for the Spring, Atlanta Coalition against Tobacco Bi-Annual Southeastern Meeting: *Tobacco and Minorities: A National Crisis*; 1994

Community Activities:

Participant, Society of General Internal Medicine (SGIM) Hill Day, March 2011
Member, Urban Research and Outreach/Engagement Center (partnership between University of Minnesota and Minneapolis Northside Community) Launch Committee; Fall 2009
"Dean" of the University of Minnesota Mini-Medical School Fall 2006 (2 weeks)
Moderated Panel on *Health Disparities in Minnesota: A Matter of Life and Death* at the Conference on Closing the Racial Disparities Gap in Minnesota; July 27, 2006
Led and conducted 20 community health fairs (over 850 attendees) at public housing developments over 20 months in Kansas City, Kansas and Missouri; 2001 – 2002
Spoke at Mason's Day, Cancer Prevention and Control, sponsored by the Kansas Masonic Foundation, Kansas City, KS; September 21, 2002
Spoke at Inside KUMC to the Kaw Valley Medical Society. The medical society for African American physicians in Kansas City. April 26, 2002
Spoke at monthly meeting of "Boule," Kansas City Chapter of an African American Fraternity of professionals, Kansas City, MO; March 2 2002
Spoke at monthly meeting of "The Midwesterner's Club of Greater Kansas City." A group of African American leaders. Kansas City, MO; October 20, 2001
Spoke at "Take Your Daughter to Work Day." KU Medical Center. Kansas City, KS; April 26, 2001
"Dean" of the University of Kansas Mini-Medical School Fall 2000 (8 weeks)
"Dean" of the University of Kansas Mini-Medical School Summer 2000 held in Topeka, Kansas

CURRICULUM VITAE FOR PROMOTION AND TENURE

DEANNA G.K. TEOH, M.D.

PROFESSIONAL ADDRESS

University of Minnesota
Department of Obstetrics, Gynecology & Women's Health
Division of Gynecologic Oncology
420 Delaware Street S.E., MMC 395
Minneapolis, MN 55455
E-mail: dkteoh@umn.edu
Business Phone: (612) 625-6503
Business Fax: (612) 626-0665

IDENTIFYING INFORMATION

Education

Degree	Institution	Date Degree Granted
B.A. *Summa Cum Laude*	Macalester College Major: Music; Minor: Biology	2000
M.D.	Medical College of Wisconsin	2004
Residency	University of California, San Francisco Obstetrics and Gynecology	2008
Fellowship	Duke University Gynecological Oncology	2011
Master's in Clinical Research	University of Minnesota	Anticipated 3/2018

Certifications and Licensure

Specialty Certification

American Board of Obstetrics and Gynecology Certification—Gynecologic Oncology	4/13/2015
American Board of Obstetrics and Gynecology Certification—Obstetrics & Gynecology	1/14/2011

Medical or Other Professional Licensure

DEA Registration (BT9770644)	11/2014-11/2020
Medical Physician and Surgeon – Minnesota (54618)	expires 4/30/2018

Academic Appointments

University of Minnesota Medical School Twin Cities Campus

Assistant Professor, Tenure Track — 2016-Present
Department of Obstetrics, Gynecology & Women's Health
Division of Gynecologic Oncology

Assistant Professor, Clinical Scholar Track — 2011-2016
Department of Obstetrics, Gynecology & Women's Health
Division of Gynecologic Oncology

Clinical/Hospital Appointments

Medical Director, HealthPartners/Regions Hospital — 2012-Present
St. Paul, MN

Staff Physician, University of Minnesota Medical Center, Fairview — 2011-Present
Minneapolis, MN

Staff Physician, Park Nicollet Health Services/Methodist Hospital — 2011-Present
St. Louis, MN

Memberships and Offices in Professional Organizations

American College of Surgeons
Fellow — 2015-Present

American Society for Colposcopy and Cervical Pathology
Member — 2015-Present
Membership Committee member — 2017-Present

American College of Obstetrics & Gynecology — 2015-Present
Fellow

Big Ten Cancer Research Consortium — 2014-Present
Co-Chair

International Society of Gynecologic Oncology — 2013-Present
Member

American Society of Clinical Oncology — 2013-Present
Member

Gynecologic Oncology Group
Member — 2011-Present
Cervix Cancer Committee Core Group member — 2015-Present
University of Minnesota co-PI — 2015-Present

Society of Gynecological Oncology(SGO)
Full Member — 2008-Present
Education Committee member — 2014-2018
Clinical Practice Committee member — 2018-Present

HONORS AND AWARDS FOR RESEARCH WORK, TEACHING, PUBLIC ENGAGEMENT, AND SERVICE

University of Minnesota

Provostial/College support to participate in the National Center for Faculty Development and Diversity (NCFDD) Faculty Success Program 2017

Office of Faculty Affairs award to participate in the Association of American Medical Colleges (AAMC) Early Career Women Faculty Leadership Development Seminar 2017

Best student research award (awarded to mentee Rebi Nahum Halloway) 2016
Powell Women's Center Research Symposium

Gynecologic Oncology Excellence in Teaching Award 2015
Gynecologic Oncology Fellows

Best Resident Research Presentation (awarded to mentee Elizabeth Slagle, MD) 2015
Konald A. Prem & Hardin E. Olson Award

Early Physician Leadership Program 2014-2017

External Sources

Named Top Doctor 2018
Minnesota Monthly Magazine

AAMC's Early Career Women Faculty Professional Development 2017

Named Twin Cities' Top Doctors – Rising Star 2017
Mpls.St.Paul Magazine

Named Twin Cities' Top Doctors – Rising Star 2016
Mpls.St.Paul Magazine

Named Twin Cities' Top Doctors – Rising Star 2015
Mpls.St.Paul Magazine

Excellence in Research Award (awarded to mentee Colleen Rivard, MD) 2013
Obstetrics & Gynecology; American College of Surgeons Clinical Congress

National Faculty Award 2013
University of Minnesota; American College of Obstetricians & Gynecologists

Resident Elected Fellow Teaching Award 2011
Duke University Medical Center, Obstetrics & Gynecology

Student Elected Fellow Teaching Award 2011
Duke University Medical Center, Obstetrics & Gynecology

Charles Hammond Research Fund Award 2009

Vaginal Cuff Study

Selected to attend: AACR Molecular Biology in Clinical Oncology 2008

Felix Rutledge Fellowship 2006
M.D. Anderson Medical Center

Best Teaching Resident Award 2006
Berlex Laboratories

Dr. and Mrs. Jack Klieger Endowed Award 2004
Obstetrics and Gynecology

Phi Beta Kappa 2000

Summa Cum Laude 2000
Macalester College

Health Professions Advisory Committee Academic Award 2000
Macalester College

Lila Bell Acheson Wallace Endowed Prize 2000

Outstanding Women in Music 1998, 1999
Samuel W. Raudenbush Endowed Prize

RESEARCH AND SCHOLARSHIP

Grants and Contracts

External Sources

Current

1. PI: Deanna G.K. Teoh
   NIH Building Interdisciplinary Research Careers in Women's Health (BIRCWH)
   "Improving Adherence to the 2012 Cervical Cancer Screening Guidelines"
   2/14/16-2/13/19
   $125,000/year

2. PI: Deanna G.K. Teoh
   KCI Investigator Initiated Trial (IIT) Grant
   "Rates of wound complications with the use of prophylactic negative pressure wound therapy in the obese gynecologic oncology population: A randomized controlled trial"
   07/01/13-06/30/18
   $5,000 + wound vac product

Completed

1. PI: Deanna G.K. Teoh
   SGO ME Strong Young Investigator Grant
   "The Urinary Microbiome in Women with Cervical Cancer: What is the impact of Primary Chemoradiation? A Pilot Study"
   1/1/15-12/31/15
   $15,000

2. PI: Deanna G.K. Teoh
   Charles Hammond Research Fund, Department of Obstetrics & Gynecology, Duke University
   Vaginal cuff dehiscence and thermal injury at the time of total laparoscopic hysterectomy: A randomized controlled trial
   1/1/10-12/31/10
   $4,000

University Sources

Current

1. K-R01 Transition Award Teoh (PI) 11/1/2018-10/31/2020
   University of Minnesota CTSI, UL1TR002494 Blazar (PI)
   Project Title: "Optimizing harms and benefits of cervical cancer screening for HPV-vaccinated women: Screening test performance and acceptability of reduced screening"

2. PI: Deanna G.K. Teoh
   Masonic Cancer Center – D2D Award
   "D2D Survey of Parent/Guardian and Adolescent Roles in HPV Vaccination Decision"
   7/1/18-12/31/18
   $7,500

3. PI: Shalini Kulasingam
   Academic Health Center Global Health Seed Grants Program
   "A comprehensive survey to identify barriers to and facilitators of cervical cancer screening in HIV positive women in Guangxi, China"
   3/1/18-2/28/2019
   $25,000

Completed

1. PI: Deanna G.K. Teoh
   Driven to Discover State Fair Grants; Masonic Cancer Center Internal Grant
   "The Impact of Social Media Messaging on Young Adult HPV Vaccination Beliefs"
   7/1/17-12/31/18
   $7,500

2. PI: Deanna G.K. Teoh
   Masonic Cancer Center BIRCWH Award
   "Improving Adherence to the 2012 National Cervical Cancer Screening Guidelines"
   1/1/2015-1/31/2016
   $125,000

University Sources

Current

1. PI: Deanna G.K. Teoh
   Tesaro
   A phase 3 Comparison of Platinum-Based Therapy with TSR-042 and Niraparib Versus Standard of Care Platinum-Based Therapy as First-Line Treatment of Stage III or IV Nonmucinous Epithelial Ovarian Cancer (FIRST)
   09/01/2018 – 08/30/2022

Publications

Peer-Review Publications

1. **Teoh D,** Shaikh R, Schnaith A, Lou E, McRee AL, Nagler RH, Vogel RI. Evaluation of graphic messages to promote human papillomavirus vaccination among young adults: A statewide cross-sectional survey. *Prev Med Rep.* 2019 Jan 11, [Epub ahead of print]

2. Shaikh R, Vogel RI, Nagler RH, Schnaith A, Lou E, McRee AL, **Teoh D**. HPV vaccination among young adults in Minnesota. *Minnesota Medicine.* 2019 Jan;102(1):38-42.

3. **Teoh D**, Hultman G, DeKam M, Isaksson Vogel R, Downs LS Jr, Geller MA, Le C, Melton G, Kulasingam S. Excess Cost of Cervical Cancer Screening Beyond Recommended Screening Ages or After Hysterectomy in a Single Institution. *J Low Genit Tract Dis*. 2018 Jul; 22(3):184-188. Epub ahead of print May 3, 2018.. PMID: 2973302

4. **Teoh D.** Is the Electronic Health Record the Answer to Improving Patient Compliance with Recommended Health Interventions? *J Womens Health (Larchmt)*. 2018 May;27(5):531-532. Epub 2018 Mar 20. PMID: 29634452

5. **Teoh D**, Smith TJ, Song M, Spirtos NM. Care after Chemotherapy: Peripheral Neuropathy, Cannabis for Symptom Control, and Mindfulness. *Am Soc Clin Onc Educ Book.* 2018 May 23;(38):469-479.

6. Lou E, Vogel RI, **Teoh D**, Hoostal S, Grad A, Gerber M, Monu M, Lukaszewski T, Deshpande J, Linden MA, Geller MA. Assessment of Circulating Tumor Cells as a Predictive Biomarker of Histology in Women with Suspected Ovarian Cancer. *Laboratory Medicine*. 2018 Mar 21;49(2):134-139. Epub 2018 Jan 19. https://doi.org/10.1093/labmed/lmx084. PMID: 29361118

7. **Teoh D,** Shaikh R, Vogel RI, Zoellner T, Carson L, Kulasingam S, Lou E. A Cross-Sectional Review of Cervical Cancer Messages on Twitter During Cervical Cancer Awareness Month. *Journal of Lower Genital Tract Disease*. 2018 Jan;22(1):8-12. PMID: 29271850

8. **Teoh D**, Isaksson Vogel R, Hultman G, Monu M, Downs L, Geller MA, Le C, Melton-Meaux G, Kulasingam S. Single Health System Adherence to 2012 Cervical Cancer Screening Guidelines at Extremes of Age and Posthysterectomy. *Obstetrics and Gynecology.* 2017 Mar;129(3):448-56. PMID: 28178049

9. Dickson EL, Stockwell E, Geller MA, Vogel RI, Mullany SA, Ghebre R, Winterhoff BJ, Downs LS Jr, Carson LF, **Teoh D**, Glasgow M, Gerber M, Rivard C, Erickson BK, Hutchins J, Argenta PA. Enhanced recovery program and length of stay after laparotomy on a gynecologic oncology service: A randomized controlled trial. *Obstet Gynecol.* 2017 Feb;129(2):355-62. PMID: 28079776

10. Argenta PA, Ballman KV, Geller MA, Carson LF, Ghebre R, Mullany SA, **Teoh DG**, Winterhoff BJ, Rivard CL, Erickson BK. The effect of photobiomodulation on chemotherapy-induced peripheral neuropathy: A randomized, sham-controlled clinical trial. Gynecol Oncol 2017 Jan;144(1):159-66. PMID: 27887804.

11. **Teoh D,** Halloway RN, Heim J, Vogel RI, Rivard C. Evaluation of the American College of Surgeons National Surgical Quality Improvement Program Surgical Risk Calculator in

Gynecologic Oncology Patients Undergoing Minimally Invasive Surgery. J Minim Invasive Gynecol 1027 Jan 1; 24(1):48-54.

12. Carson LF, Downs LS Jr, Geller MA, Ghebre R, Winterhoff B, Mullany S, **Teoh D**, Erickson B, Rivard C, Argenta PA. Implementatio of a rapid recovery protocol in gynecologic oncology surgery: A randomized controlled trial. *Obstetrics and Gynecology*. Accepted 2017.

13. Desir S, Dickson EL, Vogel RI, Thaynithy V, Wong P, **Teoh D**, Geller MA, Steer CJ, Subramanian S, Lou E. "Tunneling nanotube formation is stimulated by hypoxia in ovarian cancer cells." Oncotarget. 2016 Jul 12;7(28):43150-161. PMID: 27223082

14. Rivard C, Nahum R, Slagle E, Duininck M, Isaksson Vogel R, and **Teoh D**. Evaluation of the performance of the ACS NSQIP surgical risk calculator in gynecologic oncology patients undergoing laparotomy. *Gynecologic Oncology.* 2016 May;141(2):281-6. PMID: 26899020

15. **Teoh D.** A New Era in Cervical Cancer Screening: Balancing the Risks and Benefits of Screening. J Womens Health. 2016 Mar;25(3):207-8. Doi:10.1089/jwh.2015.5663. Epub 2016 Jan 7. PMID: 26741197

16. Rivard C, Vogel RI, **Teoh D**. Effect of intraperitoneal bupivacaine on post-operative pain in the gynecologic oncology patient. *Journal of Minimally Invasive Gynecology* 2015; doi:10.1016/j.jmig.2015.07.0713 (Epub). PMID 26216095.

17. Hutchins J, Delaney D, Vogel RI, Ghebre RG, Downs LS Jr, Carson L, Mullany S, **Teoh D**, Geller MA. Ultrasound guided subcostal transversus abdominis plane (TAP) infiltration with liposomal bupivacaine for patients undergoing robotic assisted hysterectomy: A prospective randomized controlled study. *Gynecologic Oncology* 2015; 138(3):609-13. PMID 26056753.

18. **Teoh D**, Lowery WJ, Jiang X, Ehrisman J, Halvorson P, Broadwater G, Bentley R, Secord AA, Sobolewski C, Berchuck A, Havrilesky LJ, Valea FA, Lee PS. "Vaginal cuff thermal injury by mode of colpotomy at total laparoscopic hysterectomy: A randomized clinical trial." *Journal of Minimally Invasive Gynecology*. 2015 Feb;22(2):227-33. PMID: 25305572.

19. Rivard C, Casserly K, Anderson M, Isaksson Vogel R, **Teoh D**. Factors influencing same day hospital discharge and risk factors for readmission following robotic hysterectomy in gynecologic oncology. *Journal of Minimally Invasive Gynecology*. 2015 Feb;22(2):219-26. PMID: 25304856

20. **Teoh DG**, Marriott AE, Isaksson Vogel R, Marriott RT, Lais CW, Downs LS Jr, Kulasingam SL. Adherence to the 2012 national cervical cancer screening guidelines: a pilot study. *Am J Obstet Gynecol* 2015; 212(1):62.e1-9. Doi: 10.1016/j.ajog.2014.06.057. PMID: 24992692.

21. Davidson BA, Rubatt JM, Corcoran DL, **Teoh DK**, Bernardini MQ, Grace LA, Soper WJ, Berchuck A, Siamakpour-Reihani S, Chem W, Owzar K, Murphy SK, Secord AA. "Differential angiogenic gene expression in TP53 wild-type and mutant ovarian cancer cell lines." *Frontiers in Oncology* 2014;4:163. PMID: 24999452.

22. Glasgow MA, Shields K, Vogel RI, **Teoh D**, and Argenta PA. "Postoperative readmissions following ileostomy formation among patients with a gynecologic malignancy." *Gynecologic Oncology* 2014;134(3):561-5. PMID: 24933101

23. Secord, AA, **Teoh D**, J Jia, AB Nixon, L Grace, and SK Murphy. "Dasatinib (BMS-35482) interacts synergistically with docetaxel, gemcitabine topotecan, and doxorubicin in ovarian cancer

cells with high SRC pathway activation and protein expression." *Int J Gynecol Cancer*. 24.2 (2014 Feb): 218-25. PMID: 24407585.

24. Rivard C, Dickson EL, Vogel R I, Argenta P A, **Teoh D**. The effect of anesthesia choice on post-operative outcomes in women undergoing exploratory laparotomy for a suspected gynecologic malignancy. Gynecologic oncology 2014;133(2):278-282. PMID: 24582989

25. Lopez-Acevedo M, Grace L, **Teoh D,** Whitaker R, Adams DJ, Nixon AB, Secord AA. Dasatinib (BMW-35482) potentiates the activity of gemcitabine and docetaxel in uterine leiomyosarcoma cell lines. *Gynecol Oncol Res and Practice* 2014. Doi: 10.1186/2053-6844-1-2. PMID NA.

26. Carter JS, Hutto SL, Asghar JI, **Teoh D.** Necrotizing fasciitis after placement of intraperitoneal catheter. *Gynecologic Oncology Case Reports* 2013;5:55-57. PMID: 24371698.

27. Rumer KK, Popst MD, Larivee RS, Zink M, Uyenishi J, Kramer A, **Teoh D,** Bogart K, Winn VD. Siglec-6 is expressed in gestational trophoblastic disease and affects proliferation, apoptosis and invasion. *Endocrine Related Cancer* 2012;19(6):827-40. PMID: 23089140.

28. Secord AA, **Teoh DK**, Barry WT, Yu M, Broawater G, Havrilesky LJ, Lee PS, Berchuck A, Lancaster J, Wenham RM. A phase I trial of dasatinib, an SRC-family kinase inhibitor, in combination with paclitaxel and carboplatin in patients with advanced or recurrent ovarian cancer. *Clinical Cancer Research* 2012;18(19):5489-98. PMID: 22837181.

29. **Teoh D,** Secord AA. Antiangiogenic agents in combination with chemotherapy for the treatment of epithelial ovarian cancer. *International Journal of Gynecologic Cancer* 2012;22(3):348-59. PMID: 22266932.

30. **Teoh D**, Berchuck A, Alvarez Secord A, Lee PS, Lowery WJ, Sfakianos GP, Valea FA, Myers ER, Havrilesky LJ. Cost comparison of strategies for the management of venous thromboembolic event risk following laparotomy for ovarian cancer. *Gynecologic Oncology* 2011;122(3):467-72. PMID: 21752434.

31. **Teoh D**, Won JS, Eisberg R, Nolte K, Secord AA. Severe ulceration over mandibular torus in an ovarian cancer patient receiving bevacizumab therapy. *Gynecologic Oncology Case Reports* 2011;1(1):20-21. PMID: 24371594.

32. Lacour RA, Westin SN, Meyer LA, Wingo SN, Schorge JO, Brooks R, Mutch D, Molina A, Sugphen R, Barnes M, Elder J, **Teoh D**, Powell CB, Choubey V, Blank S, Macdonald HR, Brady MF, Urbauer DL, Bodurak D, Gershenson DM, Lu KH. Improved survival in non-Ashkenazi Jewish ovarian cancer patients with BRCA1 and BRCA2 gene mutations. *Gynecologic Oncology* 2011;121(2):358-63. PMID: 21276604.

33. **Teoh DG,** Secord AA. Antiangiogenic therapies in epithelial ovarian cancer. *Cancer Control* 2011;18(1):31-43. PMID: 21273978.

34. **Teoh D**, Ayeni TA, Rubatt JM, Adams DJ, Grace L, Starr MD, Barry WT, Berchuck A, Murphy SK, Secord AA. Dasatinib (BMS-35482) has synergistic activity with paclitaxel and carboplatin in ovarian cancer cells. *Gynecologic Oncology* 2011;121(1):187-92. PMID: 21208651.

35. **Teoh D**, Freedman R, Soliman PT. Nearly 30 years of treatment for recurrent granulosa cell tumor of the ovary: A case report and review of the literature. *Case Reports in Oncology*

2010;3(1):14-18. PMID: 20740152.

36. Chan JK, Tian C, **Teoh D**, Monk BJ, Herzog T, Kapp DS, Bell J. Survival after recurrence in early-stage high-risk epithelial ovarian cancer: A Gynecologic Oncology Group study. *Gynecologic Oncology* 2010;116(3):307-11. PMID: 19944452.

37. Chan JK, **Teoh D**, Hu JM, Shin JY, Osann K, Kapp DS. Do clear cell ovarian carcinomas have poorer prognosis compared to other epithelial cell types? A study of 1,411 clear cell ovarian cancers. *Gynecologic Oncology* 2008;109(3): 370-6. PMID: 18395777.

Presentations

Invited Oral Presentations at National Professional Meetings, Conferences

1. **Teoh D**, Xiong T, Myhre A, Vogel RI. The association of risk perception, response efficacy and HPV vaccine decision making among adolescent parents/guardians. *Accepted as an oral presentation at the 2019 ASCCP Annual Scientific Meeting on Anogenital and HPV-Related Diseases. Atlanta, GA. April 2019.*

2. Speaker for Education Session. Session Title: HPV Vaccination: Why is it so difficult to implement a vaccine that prevents cancer? Presentation title: The power of social media for HPV Vaccination – Not Fake News! 6/2/2019 – 8 am. 2019 ASCO Annual Meeting in Chicago, IL.

3. Mindfulness in Gynecologic Cancer. **Teoh D.** Oral presentation at the 2018 American Society of Clinical Oncology annual meeting 6/2018.

4. Immunotherapy in Cervical Cancer. **Teoh D.** Oral presentation at the 2018 Society of Gynecologic Oncology annual meeting 3/26/18.

5. Career demands of gynecologic oncology have a substantial impact on family planning. *Song M, Kapoor A, Vogel RI, Geller MA, **Teoh D**. Oral presentation at the 2018 Society of Gynecologic Oncology annual meeting 3/26/18.
   *Presented by a clinical fellow mentee

6. Excess Cost of Cervical Cancer Screening in Women at the Extremes of Age and Post-Hysterectomy. **Teoh D,** Hultman G, DeKam M, Monu M, Vogel RI, Geller MA, Downs L, Melton-Meaux G, Kulasingam S. Oral presentation at the 2017 International Federation for Cervical Pathology and Colposcopy/American Society of Colposcopy and Cervical Pathology 4/6/17.

7. Evaluation of the National Surgical Quality Improvement Program Surgical Risk Calculator to Predict Complications in Gynecologic Oncology Patients Undergoing Laparotomy. *Rivard C, Nahum R, Slagle E, Duininck M, Isaksson Vogel R, **Teoh D.** Oral presentation at the American College of Surgeons 2015 Clinical Congress 10/6/15.
   *Presented by a clinical fellow mentee

8. The effect of anesthesia choice on post-operative outcomes in women undergoing exploratory laparotomy for gynecologic malignancy. *Rivard C, Dickson E, Isaksson-Vogel R, **Teoh D**. University of Minnesota Medical Center, Masonic Comprehensive Cancer Center. Oral Presentation at the American College of Surgeons 2013 Clinical Congress 10/7/13

*Presented by a clinical fellow mentee; Awarded an "Excellence in Research Award"

9. Cost comparison of strategies for management of venous thromboembolic event risk following laparotomy for ovarian cancer. **Teoh D**, Berchuck A, Alvarez Secord A, Lee PS, Lowery WJ, Sfakianos GP, Valea FA, Myers ER, Havrilesky LJ. Duke University Medical Center, Duke Comprehensive Cancer Center. Oral presentation at the 42nd Annual Meeting of the Society of Gynecologic Oncologists 3/6/2010.

10. Survival After Recurrence in Early Stage Epithelial Ovarian Cancer: An Analysis of GOG 157 and 95. **Teoh D**, Chan JK, Tian C, Monk BJ, Herzog T, Kapp DS, Bell J, Young RC. Department of Obstetrics & Gynecology, University of California San Francisco. Oral presentations at the Annual Western Association of Gynecologic Oncologists conference 6/2007 and the 39th Annual Meeting of the Society of Gynecologic Oncologists conference 3/2008.

Invited Oral Presentations at Local and Regional Professional Meetings, Conferences, etc.

1. Teoh D. Optimizing cervical cancer prevention. Masonic Cancer Center Seminar Series. University of Minnesota, 2/19/2019.

2. Correlation of Preoperative Hemoglobin A1C in Diabetic Patients and Postoperative Outcomes. *Gelhaus K, Rivard C, Nahum R, Isaksson Vogel R, **Teoh D.** Midwest Regional meeting of the American College of Obstetrics and Gynecology. 9/2017
*Presented by a resident mentee

3. Is the Pap test becoming extinct? **Teoh D**. University of Minnesota Department of OBGYN Grand Rounds. 12/19/2017

4. Is the Pap test becoming extinct? **Teoh D**. North Memorial Grand Rounds. 3/31/2017

5. American College of Surgeons Surgical Risk Calculator Predicts Discharge to Post-Acute Care in Older Gynecologic Oncology Patients Undergoing Laparotomy. *Shaker S, Rivard C, Nahum R, Isaksson Vogel R, **Teoh D.** Minnesota Surgical Society Fall Meeting. 10/1/16
*Presented by a resident mentee

6. The Effect of Cancer and Cancer Treatment on Sexual Health. **Teoh D**. HealthPartners Nursing CME event. 4/2/2016

7. Clinical Pathway for Management of Endometrial Cancer. **Teoh D.** Spring Research Symposium, University of Minnesota. 4/14/14

8. Separating the Zebras from the Horses. Teoh D. HealthPartners, Ob/Gyn Updat.e 4/11/2013

9. Ovarian Cancer Screening in a High-Risk Population. **Teoh D**. University of Minnesota. Minnesota Chapter of the American Congress of Obstetrics Gynecology Winter Meeting. 12/1/2012

10. Choriocarcinoma and EMACO. **Teoh D**. Regions Hospital. HealthPartners Chemo Nurse Education. 7/31/2012

11. Bevacizumab in Recurrent Ovarian Cancer. **Teoh D**, Secord AA. Duke University Medical Center, Duke Comprehensive Cancer Center. Oral presentation at the 16th Annual Winter Meeting of the Society of Gynecologic Oncologists. 2/4/2011

Poster Abstract Presentations at Professional Meetings, Conferences, etc.

1. **Teoh D**, Shaikh R, Xiong T, Bharucha J, Vogel RI, Kulasingham S, Harwood E. A cross-sectional pilot survey of health status and cervical cancer screening beliefs after 65 years of age. *Accepted as an E-poster presentation at the 2019 ASCCP Annual Scientific Meeting on Anogenital and HPV-Related Diseases. Atlanta, GA. April 4, 2019.*

2. **Teoh D**, Hultman G, Geller M, Harwood E, Le C, Vogel RI, Melton-Meaux G, Kulasingam S. Adherence to the 2012 national cervical cancer screening guidelines in women 30-65 years of age: A retrospective study. 13th Annual Women's Health Research Conference, University of Minnesota. 10/1/2018

3. Michelson ELD, Rivard Hunt C, Geller M, **Teoh D**. Complete Resection for Second-Line Ovarian Cancer Treatment. American Society of Clinical Oncology – Daily News. 5/11/2018.

4. Survey of appeal of HPV vaccine social medica graphic types in MN young adults. Shaikh R, Teoh, D. 8th Annual Cancer Research Symposium. Masonic Cancer Center, University of Minnesota. 3/29/2018.

5. Song M, Kapoor A, Vogel RI, Geller MA, **Teoh DGK**. Career Demands of Gynecologic Oncology have a Substantial Impact on Family Planning. Society of Gynecologic Oncology 49th Annual Meeting; March 23-26, 2018; New Orleans, LA.

6. #HPV Messaging on the Social Media Site @Twitter. **Teoh D,** Shaikh R, Lou E. 2017 International Federation for Cervical Pathology and Colposcopy/American Society of Colposcopy and Cervical Pathology 4/4-7/17.

7. The Predictive Value of Neutrophil:Lymphocyte Ratio and Platelet:Lymphocyte Ratio in Determining Cervical Cancer Stage. **Teoh D,** Isaksson Vogel R, Lundstrom Z, Monu M, Albertin C, Stockwell E, Rivard C, Geller M. Society of Gynecologic Oncology Annual Meeting 3/12-15/17.

8. Predictive Value of Neutrophil:Lymphocyte and Platelet:Lymphocyte Ratio and Cervical Cancer Stage. *Lundstrom Z, Isaksson Vogel R, Monu M, Albertin C, Stockwell E, Rivard C, Geller M, **Teoh D.** Masonic Cancer Research Symposium 11/3/16.
   *Presented by a student mentee

9. Cervical Cancer and Cervical Cancer Prevention Messaging on Social Media. *Shaikh R, Lou E, **Teoh D.** Masonic Cancer Center Research Symposium 11/3/16.
   *Presented by a student mentee

10. American College of Surgeons Surgical Risk Calculator Predicts Discharge to Post-Acute Care in Older Gynecologic Oncology Patients Undergoing Laparotomy. *Shaker S, Rivard C, Nahum R, Isaksson Vogel R, **Teoh D.** International Gynecologic Cancer Society Biannual Meeting 10/29-31/16.
    *Presented by a resident mentee

11. Adherence to the 2012 National Cervical Cancer Screening Guidelines at the Extremes of Age: A Retrospective Review. **Teoh D**, Hultman G, Downs L, Geller M, Harwood E, Le C, Vogel RI, Melton-Meaux G, Kulasingam K. 2016 Meeting Report of the Building Interdisciplinary

Research Careers In Women's Health (BIRCWH) annual meeting 6/8/16.

12. The American College of Surgeons National Surgical Quality Improvement Program (ACS NSQIP) Surgical Risk calculator Predicts Discharge to TCU for Gynecologic Oncology Patients undergoing Minimally Invasive Surgery. *Nahum R, Rivard C, Heim J, Isaksson Vogel R, **Teoh D.** University of Minnesota & Masonic Comprehensive Cancer Center. Poster presentation at the 2016 University of Minnesota Powell Women's Center Research Day 4/4/16.
*Presented by a student mentee; Awarded a Poster Award.

13. Adherence to the 2012 National Cervical Cancer Screening Guidelines at the Extremes of Age: A Retrospective Review. **Teoh D,** Hultman G, Downs L, Geller M, Harwood E, Le C, Isaksson Vogel R, Melton-Meaux G, Kulasingam S. University of Minnesota & Masonic Comprehensive Cancer Center. Poster presentation at the 2016 University of Minnesota Powel Women's Center Research Day 4/4/16.

14. Evaluation of the NSQIP Surgical Risk Calculator to Predict Complications in Gynecologic Oncology Patients Undergoing Laparotomy. Rivard C, Slagle E, Nahum E, Isaksson Vogel R, **Teoh D.** University of Minnesota & Masonic Comprehensive Cancer Center. Featured Poster presentation at the 2015 Society of Gynecologic Oncology annual meeting 3/2015.

15. Pap Hub: A system to improve compliance with pap smear screening guidelines in a large healthcare system. **Teoh D**, Fall LA, Beitelspacher EA. University of Minnesota Medical Center, Masonic Comprehensive Cancer Center & Healthpartners. Poster presentation at the 2013 American Society of Clinical Oncology's Quality Care Symposium 11/2/2013.

16. Dasatinib (BMS-354825), a SRC inhibitor, has synergistic activity with paclitaxel and carboplatin in ovarian cancer cell lines. **Teoh D**, Ayeni TA, Rubatt JM, Whitaker RS, Dressman HK, Adams DJ, Berchuck A, Murphy SK, Secord AA. Duke University Medical Center, Duke Comprehensive Cancer Center. Poster presentations at the 100th Annual Meeting of the American Association for Cancer Research 4/19/2009, and the 41st Annual Meeting of the Society of Gynecologic Oncologists 3/2010.

17. Do clear cell ovarian carcinomas have poorer prognosis compared to other epithelial cell types? A study of 1,411 clear cell ovarian cancers. **Teoh D,** Chan JK, Hu JM, Shin JY, Osann K, Kapp DS. Department of Obstetrics & Gynecology, University of California San Francisco. Poster presentation at the 39th Annual Meeting of the Society of Gynecologic Oncologists 3/2008.

18. Invasive Markers in Human Gestational Trophoblastic Disease. **Teoh D**, Chen L, Winn VD. Department of Obstetrics & Gynecology, University of California San Francisco. Poster presentation at the Western Association of Gynecologic Oncologists conference 6/2007.

TEACHING AND CURRICULUM DEVELOPMENT

University of Minnesota

Course/Lecture List

Why we vaccinate: an update on HPV related disease	8/28/2018
Chemotherapy Jeopardy UMN Gynecologic Oncology Education Conference	3/31/2016
Gynecologic Anatomy Review	1/12/2015

UMN Obstetrics & Gynecology Resident Lecture

Vaginal Cancer 3/28/2014
UMN Gynecologic Oncology Education Conference

Ovarian Cancer Screening & Diagnostic Tests: Beyond CA-125 2/25/2013
UMN Obstetrics & Gynecology Resident Lecture

Delayed Management of Placenta Percreta 9/27/2012
UMN Gynecologic Oncology Education Day

Gestational Trophoblastic Disease: The True "Fetoma" 7/2/2012
UMN Obstetrics & Gynecology Resident Lecture

HPV-Related Gyn Diseases: To cut is to cure…or is it? 2/28/2012
UMN Radiation Oncology lecture

Gestational Trophoblastic Disease and Placental Site Trophoblastic Tumors 2/7/2012
UMN Gynecologic Oncology Education Conference

Biweekly Pathology Conference 2011-Present
UMN Gynecologic Oncology Fellows and OBGYN Residents at Regions Hospital

Ovarian Cancer: Everything you need to know (for the boards and beyond) 11/23/2011
UMN Medicine Core Conference presentation

Duke University

Femme Fatale: Thromboembolism in Obstetrics & Gynecology 3/30/2011
Grand Rounds presentation

Ovarian Cancer Clinical Trials Program at Duke University 10/9/2009
Oral Presentation at "Day at Duke"
Teoh D, Secord AA

ADVISING AND MENTORING

Undergraduate Student Activities

Undergraduate Advising

Pre-Med American Medical Student Association 2013-Present
Provide Mentorship to premed students interested in GynOnc & Ob/Gyn

Graduate Student Activities

Curriculum development for the Gyn Onc Fellow Education Conferences 2011-Present

Student Research Mentees

Adam Langer, Medical Student 9/2017-Present
Rida Shaikh, Pre-med student 9/2016-Present
Taylor Zoellner, Pre-med student Summers 2016-2018

McKenzie DeKam, Medical Student 2016-Present
Minnu Monu, Visiting Medical Student 10/2015-1/2016
Zachary Lundstrom, Medical Student 2015-Present
Rebi Nahum, Medical Student 2014-Present
Megan Duinick, Medical Student Summer 2014

Resident Research Mentees

Cassandra Albertin, M.D 2015-2017
Resident in the Department of Ob/Gyn
Project: Does Neutrophil:Lymphocyte Ratio (NLR) and/or Platelet:Lymphocyte Ratio (PLR) have prognostic significance in cervical cancer?

Salma Shaker, M.D. 2015-present
Resident in the Department of Ob/Gyn
Project: Evaluation of the NSQIP surgical risk calculator to predict discharge to a skilled nursing facility in the older gynecologic oncology patient population
Project: Using the NSQIP calculator to predict the disposition of older gynecologic oncology patients following cancer surgery

Jennifer Heim, M.D. 2015-2016
Resident in the Department of Ob/Gyn
Project: Evaluation of the NSQIP surgical risk calculator to predict complications in gynecologic oncology patients undergoing laparoscopy

Kelsey Gelhaus, M.D. 2015-present
Resident in the Department of Ob/Gyn
Project: Correlation of preoperative hemoglobin A1C and glucose with surgical outcomes
Project: Association between preoperative HgbAlc levels and perioperative complications

Elizabeth Slagle, M.D. 2013-2015
Resident in the Department of Ob/Gyn
Project: Evaluation of the NSQIP surgical risk calculator to predict complications in gynecologic oncology patients undergoing laparotomy

Bradley Burger, M.D. 2013-2015
Resident in the Department of Ob/Gyn
Project: Patients' goals for care undergoing treatment by a gynecologic oncologist: Are they different from the practitioners?

Kelly Casserly, M.D. 2013-2014
Resident in the Department of Ob/Gyn
Project: Factors influencing same-day discharge and risk factors for readmissions after robotic-assisted laparoscopic surgery in Gynecologic Oncology

Amity Marriott, M.D. 2012-2015
Resident in the Department of Ob/Gyn
Project: Adherence to the 2012 National Cervical Cancer Screening Guidelines within a single health maintenance organization: A pilot study

Post-doctoral Fellows Supervised

Mihae Song, M.D., Gynecologic Oncology Fellow 2015-present
(Faculty Advisor)

Colleen Rivard, M.D., Gynecologic Oncology Fellow 2011-2015
(Faculty Advisor)

CLINICAL SERVICE

Clinical Service Responsibilities

Clinical Inpatient On-call Service (approximately 7-8 weeks per year)

During an on call week (7 a.m. Monday through 7 a.m. the following Monday), I am responsible for all consults, emergency room visits, emergent surgical cases, and for rounding on the inpatient service which can range 10-20 patients. The inpatient service is made up of post-operative patients, patients receiving chemotherapy, radiation therapy and patients admitted for acute issues. During the on call week I lead daily teaching rounds for the residents (one resident from each PGY 1-4), 3rd year medical students, 4th year sub-Interns, Gynecology Oncology fellows and one physician assistant. We conduct a 30 minute teaching round including a formal presentation by me or one of the inpatient team members. Additionally, I am responsible during my call week for patients at Park Nicollet Methodist Hospital and Regions Hospital. On the weekends I round at all three hospitals on the inpatient service and am responsible for any gynecologic oncology surgical cases or admits at these affiliate hospitals.

Regions Hospital

The inpatient service at Regions Hospital is made up of post-operative patients, patients receiving chemotherapy, radiation therapy and patients admitted for acute issues. During rounding (approximately two times per week) I lead teaching rounds for residents. I hold approximately 1 full-day outpatient clinic per week and I perform surgical procedures on average of 8 -12 patients per month.

PROFESSIONAL SERVICE AND PUBLIC OUTREACH

Service to the Discipline

Course Directorship

Education Session: Care after Chemotherapy: Treating the Body and Mind 06/04/2018
American Society of Clinical Oncology annual meeting

Postgraduate Educational Forum on HPV and Cervical Cancer 03/26/2018
Society of Gynecologic Oncology annual meeting

Editorships/Journal Reviewer Experience

Ad-Hoc Reviewer

Gynecologic Oncology	2018-Present
Preventative Medicine	2017-Present
Journal of Women's Health	2015-Present
American Journal of Preventative Medicine	2015-Present
International Journal of Gynecologic Cancer	2014-Present

Review Board

ABOG Oral Board Reviewer November 2018-Present

Committee Memberships

ASCCP 2018- Present
Treatment Working Group Member
"Help to develop and update the 2012 Consensus Guidelines for Managing Abnormal Cervical Cancer Screening Tests and Cancer Precursors."

American Society of Clinical Oncology 2018-Present
Social Media Working Group Member

American Society of Colposcopy and Clinical Pathology 2017-Present
Role: Membership Committee member

Big Ten Cancer Research Consortium Gynecologic Cancer Committee 2015-Present
Role: co-chair

NRG Oncology 2011-Present
Role: UMN site co-PI (2015-present)
Cervix Cancer Committee Core Member (1/2016-presenet)

Society of Gynecologic Oncology Education Committee 2014-Present
Role: Develop Education Programs for SGO members

American College of Obstetrics & Gynecology PROLOG task force 2014-2015
Role: Produce the 2014 edition of PROLOG Gynecologic Oncology

HealthPartners Robotics Peer Review Committee 2014-2015
Role: Review complications of robotic surgery and advise corrective action if indicated

The Obesity Society Abstract Review Committee 2013
Role: Reviewed abstracts for the 2013 annual meeting

Health Partners Pap Hub Committee 2012-Present
Role: Advise pap smear practice for the HealthPartners healthcare system

Health Partners Robotic Committee 2012-Present
Role: Advise efficient use and data collection for robotic procedures

Service to the University Of Minnesota

PSI 12 and DVT Standardization 2017-Present
Co-chair

Masonic Cancer Center Building Interdisciplinary Research 2015-2016
Careers in Women's Health (BIRCWH) scholar

Masonic Cancer Center Cancer Protocol Review Committee 2014-Present
Role: Review cancer clinical trial protocols for scientific integrity

Organization of conferences, workshops, panels, symposia

GynOnc Spring Research Symposium — April 5, 2018
Organized conference and speakers

Community Outreach Activities

Ask Anything! GOLD Event — October 18, 2018
Invited speaker at outreach group for patients with ovarian cancer

HPV vaccination and Cancer Research at the University of Minnesota
Interview with WCCO Radio — August 31, 2017

HPV Presentation, University of Minnesota Building — August 31, 2017
Minnesota State Fair

ACA repeal could greatly impact women's health (commentary)
UMN AHC Health Talk — February 22, 2017

New study shows higher rates of cervical cancer (commentary)
Minnesota News Network — February 7, 2017

Women and Cancer Panel
Macalester College division of Colleges against Cancer — April 21, 2016

Nominations to Product Development Peer Review Panels

- Anant Madabhushi
- Amy Trainor
- Bin Zheng

ANANT MADABHUSHI, Ph.D.
F. Alex Nason Professor II
Department of Biomedical Engineering
Director, Center for Computational Imaging and Personalized Diagnostics (CCIPD)
Case Western Reserve University
2071 Martin Luther King Drive, Wickenden 523, Cleveland, Ohio 44106-7207,
Tel: (216) 368-8519, Fax: (216) 368-4969
anant.madabhushi@case.edu (email)
http://ccipd.case.edu/
Wikipedia: https://en.wikipedia.org/wiki/Anant_Madabhushi

A. EDUCATION/TRAINING

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	YEAR(s)	FIELD OF STUDY
Mumbai University, MGM College of Eng.	B.E	1994-1998	Biomedical Eng.
University of Texas, Austin	M.S.	1998-2000	Biomedical Eng.
University of Pennsylvania	PhD	2000-2004	Bioengineering

B. PROFESSIONAL EXPERIENCE

B.1. Academic

Cleveland Functional Electrical Stimulation (FES) Center
2018-Present
Investigator

Case Western Reserve University (CWRU), Department of Biomedical Engineering (BME)
2016-Present
F. Alex Nason Professor II

2014-2016 Professor

2012-2014
Associate Professor

Center for Computational Imaging and Personalized Diagnostics, CWRU
2012-present Director

Cleveland Digestive Diseases Research Core Center, CWRU
2016-present Associate Member

Case Comprehensive Cancer Center, CWRU
2013-present Member

Case Western Reserve University (CWRU), Department of Electrical Engineering and Computer Science (EECS)
2015-present Professor (Secondary)
2013-2015 Associate Professor (Secondary)

Case Western Reserve University (CWRU), Division of General Medical Sciences-Oncology
2015-present Professor (Secondary)
2013-2015 Associate Professor (Secondary)

Case Western Reserve University (CWRU), Department of Urology
2015-present Professor (Secondary)
2013-2015 Associate Professor (Secondary)

Case Western Reserve University (CWRU), Department of Radiology
2015-present Professor (Secondary)
2013-2015 Associate Professor (Secondary)

Case Western Reserve University (CWRU), Department of Pathology
2015-present Professor (Secondary)
2013-2015 Associate Professor (Secondary)

Case Western Reserve University (CWRU), Department of Radiation Oncology
2015-present Professor (Secondary)

Lerner Research Institute, Cleveland Clinic
2017-present Adjunct Professor

Boston Medical Center, Department of Radiology
2011-present Adjunct Associate Professor

Hospital at the University of Pennsylvania, Department of Surgical Pathology
2011-present Adjunct Associate Professor

Rutgers University, Department of Biomedical Engineering
2010-2012 Associate Professor
2005-2010 Assistant Professor
2004-2005 Assistant Research Professor

Rutgers University, Department of Electrical and Computer Engineering

2011-2012 Associate Professor (Secondary)

University of Medicine and Dentistry of New Jersey, Department of Radiology
2007-2012 Adjunct Assistant Professor

Cancer Institute of New Jersey
2007-2012 Full Member

University of Pennsylvania, Department of Bioengineering
2000-2004 Graduate Research Assistant

University of Texas, Austin, Department of Biomedical Engineering
1998-2000 Graduate Research Assistant

B.2. Industry

Merck
2018-present Scientific Consultant

Astrazeneca
2017-present Tumor Modeling Scientific Advisory Board Member

Inspirata Inc.
2014-present Scientific Consultant

Ibris Inc.
2010-2015 Co-Founder and Chairman of the Board

Elucid Bioimaging
2013-2014 Scientific Advisory Board Member

vascuVis Inc.
2011-2013 Co-Founder and Chief Technical Officer

Siemens Corporate Research
2000-2001 Engineering Intern

C. HONORS, AWARDS AND RECOGNITION

- Finalist, Diekhoff Mentorship and Teaching Awards, Case Western Reserve University, 2018.
- Fundraising Leadership Award, Case School of Engineering, 2018.

- Top 100 Read Oncology papers in Scientific Reports for 2017 "Prediction of recurrence in early stage non-small cell lung cancer using computer extracted nuclear features from digital H&E images".
- Honorable Mention for "Sedeen: An extensible viewer for digital pathology", Live Demonstration Workshop, The International Society for Optics and Photonics (SPIE) Medical Imaging, 2018
- "Differentiating recurrent glioblastoma multiforme from radiation induced effects via texture analysis on multi-parametric MRI", The International Society for Optics and Photonics (SPIE) Medical Imaging, February 17th, 2014.
- Certificate of Commendation, NeuroRadVision Vision Team, Ohio Secretary of State, Members of the House of Representatives of the 132nd General Assembly of Ohio, July 21st, 2017.
- **2017 IEEE Engineering in Medicine and Biology Society (EMBS) Technical Achievement Award** " "For contributions in computer aided diagnosis, pattern recognition, machine learning and image analysis tools for diagnosis, prognosis, and treatment response prediction of disease from digital pathology and radiographic images."
- "Most Popular Article Published in Journal of Pathology Informatics 2016", Awarded for "Deep learning for digital pathology image analysis: A comprehensive tutorial with selected use cases", Andrew Janowczyk, Anant Madabhushi, J Pathol Inform 2016, 7:29 (26 July 2016) at Association of Pathology Informatics Summit 2017, Pittsburgh, PA, May 24th, 2017.
- Participant, Coalition for Imaging and Bioengineering Research (CIBR) 2017 Medical Imaging Technology Showcase, The Academy for Radiology & Biomedical Imaging Research Hart Senate Office Building, Washington DC, March 28th, 2017.
- NIH Study Section (Standing), Biodata Management and Analysis, July 1, 2017-June 30, 2021.
- Paper "Computer-Extracted Texture Features to Distinguish Cerebral Radionecrosis from Recurrent Brain Tumors on Multiparametric MRI: A Feasibility Study" nominated for the annual Lucien Levy Best Research Article Award, American Journal of Neuroradiology, 2017.
- High-end Foreign Expert Award, Chinese State Administration of Foreign Experts Affairs 2016.
- Images featured on cover of Journal of European Urology, April 2016.
- **Selected as Crain's Cleveland Business Forty under 40, 2015**
- Selected as Member of I-Corps@Ohio Summer Cohort, 2015.
- Associate member of The Cleveland Digestive Diseases Research P30 Core Center
- **Associate Member, NCI Quantitative Imaging Network, 2015.**
- **Fellow, American Institute for Medical and Biological Engineering, 2015.**
- Recognized Reviewer Status, European Journal of Radiology, 2014.
- Invited Participant, AAPM Forem on Imaging Genomics, MD Anderson, Houston, TX September 30-October 1, 2014
- Paper "Computerized Image Analysis for Identifying Triple-Negative Breast Cancers and Differentiating Them from Other Molecular Subtypes of Breast Cancer on Dynamic Contrast-enhanced MR Images: A Feasibility Study" featured in "This Month in Radiology", June 2014.
- **Innovation Award, Case School of Engineering, 2014**

- Honorable mention award, Neurology Research Day, Case Western Reserve University for **"**Computerized texture descriptors to distinguish radiation necrosis from recurrent brain tumors on MRI", April 15th, 2014.
- **CDMRP New Investigator Award for Lung Cancer, 2014.**
- Honorable Mention for Best Poster Presentation, Conference on Computer Aided Diagnosis for "Differentiating recurrent glioblastoma multiforme from radiation induced effects via texture analysis on multi-parametric MRI", The International Society for Optics and Photonics (SPIE) Medical Imaging, February 17th, 2014.
- Cum Laude for Best Poster Presentation, Conference on Image Guided Interventions for "Identifying MRI markers to evaluate early treatment related changes post laser ablation for cancer pain management", The International Society for Optics and Photonics (SPIE) Medical Imaging, 2014.
- First place Scientific award for "Bias field correction and intensity standardization improve the diagnostic accuracy of multi-parametric MRI in computerized detection of prostate cancer *in vivo*" at the Society for Imaging Informatics in Medicine (SIIM) meeting, Dallas, TX, June 7th, 2013
- First Place in "National Cancer Institute International Society for Biomedical Imaging (NCI-ISBI) 2013 Challenge - Automated Segmentation of Prostate Structures" held in conjunction with Institute of Electrical and Electronics Engineers (IEEE) International Symposium on Biomedical Imaging, San Francisco, CA, April 7th, 2013.
- Paper "Spectral embedding based active contour (SEAC) for lesion segmentation on breast dynamic contrast enhanced magnetic resonance imaging" featured on cover of Medical Physics, April 2013.
- Radiological Society of North America (RSNA) Abstract "Computer-aided Detection of Peripheral Zone and Central Gland Prostate Tumors on T2-weighted MRI", Featured on AuntMinnie.com in the Advanced Visualization preview, 2012.
- Runner Up for Investors Choice Award, New Jersey Entrepreneurial Network (NJEN), 2012.
- Paper "Concurrent segmentation of the prostate on MRI and CT via linked statistical shape models for radiotherapy planning", Highlighted in Medical Physics Editors Pick Column, 2012.
- First Prize, SNR Denton Elevator Pitch Competition, Rutgers Entrepreneurship Day, 2011
- Invited Participant, National Academies Keck Futures Initiative (NAKFI) conference on Imaging Science, 2010.
- **Coulter Fellow, Wallace H. Coulter Foundation for Translational Research, 2010.**
- Rutgers Faculty Academic Service Increment Program (FASIP) Award for Teaching, Research, 2009
- **Early Career Award (Phase 2), Wallace H. Coulter Foundation for Translational Research**, **2008.**
- Rutgers Faculty Academic Service Increment Program (FASIP) Merit Award for Teaching, Research, 2006-2011
- Life Sciences Commercialization Award, Office of Corporate Liaison and Technology Transfer (OCLTT), Rutgers, 2008-09
- Society for Imaging Informatics in Medicine (SIIM) Research Award, 2008-09
- Rutgers Faculty Academic Service Increment Program (FASIP) Award for Teaching, Research, 2007
- New Investigator Award, Cancer Institute of New Jersey, 2007.

- Technology Commercialization Award, Office of Tech Transfer, Rutgers University, 2006.
- Charles and Johanna Busch Biomedical Research Award, 2006.
- **Early Career Award (Phase 1), Walter H. Coulter Foundation for Translational Research, 2006.**
- Third prize for Oral Presentation at Institute of Electrical and Electronics Engineers Northeast Bioengineering Conference (IEEE NEBE), Philadelphia, PA, 2002.
- RAMS HORN award for Best Image Processing Project, University of Texas, Austin, TX, 2000.

Media Recognition

- *"Truly, Neurally, Deeply",* Knowable Magazine, October 26th, 2018.
- *"Graduate student Nathaniel Braman wins Radiological Society of North America award",* The Daily, October 19th, 2018.
- *"Stable and discriminating features are predictive of cancer presence and Gleason grade in radical prostatectomy specimens: a multi-site study.",* Featured on UroToday, October 12th, 2018.
- *"Case School of Engineering alumni couple, retired after careers at Apple, commit gift to computer imaging lab",* The Daily, September 24th, 2018.
- *"Behind the Scenes Cancer Research Lab: Be Well Facebook Live"*, The Daily, September 20th, 2018.
- *"Researchers look to immune cell shapes to predict how well body will fight lung cancers",* Press Release, September 20th, 2018.
- *"Six Biomedical University Technologies Receive Full-Funding"*, Press Release, September 18th, 2018.
- *"CWRU researchers granted breast cancer imaging patent",* The Daily, September 14th, 2018.
- *"Identifying the morphologic basis for radiomic features in distinguishing different Gleason grades of prostate cancer on MRI: Preliminary findings",* UroToday, September 6th, 2018.
- *"Out-doctoring the Doctor",* Communications of the ACM, August 21st, 2018.
- *"How Artificial Intelligence is Changing Radiology, Pathology",* HealthIT Analytics, August 3rd, 2018.
- "*Center for Computational Imaging and Personalized Diagnostics researchers awarded patent",* The Daily, July 27th, 2018.
- "*How man and machine can work together to diagnose diseases in medical scans*", Article by Anant Madabhushi and Kaustav Bera featured in The Conversation, July 17th, 2018.
- Work on Breast Cancer Diagnostics referenced in *"Collaboration scores $46 million to improve region's health"*, The Daily, June 26th, 2018.
- *"Case Comprehensive Cancer Center earns 'exceptional' rating, $31.9 million in grants for research and education from National Cancer Institute"*, The Daily, June 22nd, 2018.
- *"Funding Rolls in for Computational Imaging Research",* Case Western Reserve Biomedical Engineering Spring 2018 Newsletter, Spring, 2018.
- *"Are doctors obsolete? "Deep learning" AI system trounced doctors in predicting heart failure in patients, boasting 97 percent accuracy",* Natural News, May 24th, 2018.
- *Work in CCIPD featured on WEWS Channel 5*, May 13th, 2018.
- *"With Training, Startups Like Paige.AI Could Soon Diagnose Cancer",* Xconomy, May 14th,

DIANE AMY TRAINOR, Ph.D.

9 Carillon Court
Wilmington, DE 19803
Home: 302-428-1677
Cell: 302-598-5288
datrainor55@gmail.com

SUMMARY

- Innovative product discovery and development leader with 29+ years of experience and a proven track record of delivery across a broad range of therapeutic areas.
- Extensive in-depth leadership experience in Pharmaceuticals product discovery and product strategy development /execution.
- Creates and leads high performing teams by providing a challenging, open, and supportive environment. Maintains team motivation and focus under pressure. Demonstrates infectious enthusiasm, energy and confidence.
- Senior leadership role as a core team member of the AstraZeneca Neuroscience Therapeutic Area Leadership team responsible for NS strategy development and products and licensing governance.
- Broad experience in in-licensing – due diligence and product development strategy
- Senior leadership role in alliance development and management
- Designed and led Phase II After Action Review of all NS projects and implemented learning to create a new climate of courageous conversations and decision-making, knowledge sharing and continuous improvement, and mandatory functional alignment.
- Extensive external leadership experience including chair of NIH Bioorganic Natural Products Study Section and invited member of the NIH National Advisory General Medical Sciences Council.

EXPERIENCE

BIOMOTIV – The Harrington Project for Discovery and Development 2012-Present
Venture Partner

- Project Director R&D- Dual Therapeutics LLC- late stage discovery/early development oncology program stemming from an academic discovery project
- Project Director R&D – Z53 Therapeutics LLC- mid stage discovery oncology program stemming from an academic discovery project
- Project Lead- BioMotiv and Biogen Strategic Partnership in Neuroscience
- Due diligence and portfolio management in a bio-accelerator environment

TRAINOR CONSULTING, LLC 2011-Present
Partner, Executive Pharmaceutical Consultant

- Consulting services on all aspects of pharmaceutical discovery and development.

- Special expertise in conducting due diligence behind firewalls on programs, lead series, and drug candidates.
- Special expertise in creating mid-late stage research and Ph1/II development plans

ASTRAZENECA PHARMACEUTICALS, Wilmington, DE
Formerly: Zeneca and ICI

DEVELOPMENT LEADERSHIP ROLES –ASTRAZENECA AND ZENECA

- ***Neuroscience Global External Partnerships Director (2006-2010)***

Accountable for development and execution of the NS alliances and partnering strategy with the goal of securing a leading NS portfolio and reputation in line with business goals. Focused on alliance development to sustain a portfolio of products, provide discovery and development capabilities and shape the environment to support development of new medicines. Culminated in a well- integrated package of collaborations with key academic centers, institutes and government agencies worldwide with active AZ participation and management and supported by creative deal structures.

Global Product Director, Oncology (2002-2006)

Accountable for leadership of cross -functional and cross -cultural senior development teams to set fast and effective product development strategies and timely effective delivery. Led multiple teams over a 4-year period covering candidate nomination through delivery of Phase II results. Some key GPD roles: Iressa Breast Cancer, AZD6126, Zibotetan(ZD4054) and Recentin (ZD2171)

a. Led the Iressa Breast Cancer team in the creation and implementation of a well-designed development strategy and clinical plan.
b. Led closure of the ZD6126 clinical program working closely with the licensing partner, Angiogene. Recognized as accomplished in a very professional way, excellent working with internal and external stakeholders, best closure ever
c. Led the ZD4054 team in the delivery of POP ahead of schedule, achieved FDA Fast Track Status, and started Phase II pivotal trial.
d. Gained business support with budget to explore an accelerated development option for AZD2171
e. Led the AZD2171 in the delivery of POP, Phase I trial delivery, and creation of development for launch scenarios for TG3
f. Played a key role in securing CRADA agreement with the NCI for AZD2171 by successfully communicating that AZD2171 is the best VEGFR TKI in the business and demonstrating commitment to the collaboration

US Director of Emerging Products, Oncology (2001-2002)

Responsible for creating and integrating a cross -functional US product development view into global strategies by successfully partnering with the Global Product Teams.

Global Product Director, CNS – Emerging Products (1999-2000)

Accountable for global strategy development and execution of early stage drug development projects in Neuroscience. Led a project to monitor the competitive environment to identify future CNS in-licensing candidates

Single Strategy Team Chair (SST) – (1998-1999)

Arthritis and Biopharmaceutical Cancer Projects- Led the team in advancing several candidates for arthritis and successfully closed down suboptimal biopharmaceutical projects

DISCOVERY LEADERSHIP ROLES-ZENECA

International Projects Manager, Research- (1997-1998)

Led an international cross functional R&D team in the design of a novel Integrated R&D Drug Discovery Process for Zeneca - Process Adopted in 1Q98

Co-leader Medicinal Chemistry Department (CNS and Respiratory) (1995-1996)

led the CNS team in the discovery and delivery of several drug development candidates in the areas of schizophrenia and stroke

EXTERNAL LEADERSHIP ROLES

- Medicinal Chemistry Division, American Chemical Society

  Division Chair, 2001 and Secretary/Program Chair, 1999

- National Institute of Health: National Advisory General Medical Science Council- Invited Member

- National Institute of Health: Bio-Organic/Natural Products Study Section

  Chairperson: 1991-1993- Led a team of senior academic scientists in the review of all grant proposals in the bio-organic field for the NIH- 3X/yr
  Member: 1989-1991-reviewed, rated and ranked NIH grant proposals-3X/yr

- Co-Chair, Bioorganic Gordon Conference

EDUCATION

1979-1981 **Columbia University**

NIH Postdoctoral Fellow- Koji Nakanishi
Structure Elucidation of a Prostaglandin Polymer, Iron-Chelator, Ecdysones, and Marine Toxins

1975-1979 **Brandeis University**
Ph.D. in Organic Chemistry received July, 1979
Research Advisor: Professor Ronald Parry
Biosynthesis of Biotin and Lipoic Acid.

1971-1975 **Stevens Institute of Technology**
BS in Chemistry. Undergraduate Research with Dr. Ajay K. Bose

PUBLICATIONS

Ohnmacht, Cyrus J.; Russell, Keith; Empfield, James R.; Frank, Cathy A.; Gibson, Keith H.; Mayhugh, Daniel R.; McLaren, Frances M.; Shapiro, Howard S.; Brown, Frederick J.; Trainor, Diana A.; Ceccarelli, Christopher; Lin, Margaret M.; Masek, Brian B.; Forst, Janet M.; Harris, Robert J.; Hulsizer, James M.; Lewis, Joseph J.; Silverman, Stuart M.; Smith, Reed W.; Warwick, Paul J.; Kau, Sen T.; Chun, Alexa L.; Grant, Thomas L.; Howe, Burton B.; Li, Jack H.; Trivedi, Shephali; Halterman, Tracy J.; Yochim, Christopher; Dyroff, Martin C.; Kirkland, M.; Neilson Kathleen L.; N-Aryl-3,3,3-trifluoro-2-hydroxy-2-methylpropanamides: KATP Potassium Channel Openers, Modifications on the Western Region. J. Med. Chem.,40(6), 1048 1997

Ohnmacht, C J; Russell K; Empfield JR; Frank C A; Gibson, K H; Mayhugh D R; McLaren F M; Shapiro H S; Brown F J; Trainor D A; Ceccarelli C; Lin M M; Masek B B; Forst J M; Harris R J; Hulsizer J M; Lewis J J; Silverman S M; Smith R W; Warwick P J; Kau S T; Chun A L; Grant T L; Howe B B; Neilson K L; N-Aryl-3,3,3-trifluoro-2-hydroxy-2-methylpropanamides: KATP Potassium Openers, Modifications on the Western Region. Journal of Medicinal Chemistry, (1996 Nov 8) 39 (23) 4592-601

Jackson P F; Cole D C; Slusher B S; Stetz S L; Ross L E; Donzanti B A; Trainor D A; Design, synthesis and biological activity of a potent inhibitor of the neuropeptidase N-acetylated alpha-linked acidic dipeptidase. Journal of Medicinal Chemistry, (1996 Jan 19) 39 (2) 619-22

Li J H; Yasay G D; Kau S T; Ohnmacht C J; Trainor D A; Bonev A D; Heppner T J; Nelson M T; Studies of the K(ATP) channel opening activity of the new dihydropyridine compound 9-(3-cyanophenyl)-3,4,6,7,9,10-hexahydro-1,8-(2H,5H)-acridined ione in bladder detrusor in vitro. Arzneimittel-Forschung, (1996 May) 46 (5) 525-30

Klimas M T; Goldstein J M; Trainor D A; Jacobs R T; Ohnmacht C J; Roberts R A; Yee Y K; Terpko M O; Thomas S P; Cronk L A; Frank C A; Harris G D; Hulsizer J; Lewis J J; McLaren F M; Mauger R C; Morosky G D; Ronkin S M; Sienkewicz P; Putative atypical antipsychotics

with mixed dopaminergic (D1, D2) and serotonergic (5HT2) activity: The design evolution of ZD3638. Bioorganic and Medicinal Chemistry Letters 5/16 (1795-1800) 1995

Howe B B; Halterman T J; Yochim C; Do M L; Pettinger S J; Stow R B; Ohnmacht C J; Russell K; Empfield J R; Trainor D A; Zeneca ZD6169: A novel KATP channel opener with in vivo selectivity for urinary bladder. Journal of Pharmacology and Experimental Therapeutics, (1996 Aug) 274(2)884-90

Trivedi S; Potter-Lee L; Li J H; Yasay G D; Russell K; Ohnmacht C J; Empfield J R; Trainor D A; Kau S T; Calcium dependent K-channels in guinea pig and human urinary bladder. Biochemical and Biophysical Research Communications, (1995 Aug 15) 213(2) 404-9

Trivedi S; Stetz S L; Potter-Lee L; McConville M; Li J H, Empfield J; Ohnmacht C J; Russell K; Brown F J; Trainor D A; K-channel opening activity of ZD6169 and its analogs: effect on 86Rb efflux and 3H-P1075 binding in bladder smooth muscle. Pharmacology, (1996 Jun) 50 (6) 388-97

Trivedi S; Potter-Lee L; McConville M W; Li J H; Ohnmacht C. J; Trainor D A; Kau S T; K-channel opening activity of dihydropyridine ZM244085: effect on 86Rb efflux and 3H-P075 binding in urinary bladder smooth muscle. Research Communications in Molecular Pathology and Pharmacology, (1995 May) 88(2) 137-51

Li J H; Yasay G D; Zografos P; Kau S T; Ohnmacht C J; Russell K; Empfield J R; Brown F J; Trainor D A; Bonev A D; Zeneca ZD6169 and its analogs from a novel series of anilide tertiary carbinols: in vitro KATP channel opening activity in bladder detrusor. Pharmacology, (1995 Jun)51(1)33-42

Ohnmacht C J; Russell K; Frank C A; Gibson K; McLaren F M; Shapiro H S; Brown F J; Trainor D A; Empfield J R; Forst J M; Harris R. J; Hulsizer J M; Lewis J J; Mayhugh D R; Silverman S M; Smith R W/ Warwick P J; The discovery of bladder selective K-ATP openers in a series of anilide tertiary carbiols: The selection of ZD6169. USA FASEB Journal Experimental Biology (April 24-28, 1994)

Frank C A; Forst J M; Grant T; Harris R J; Kau S T; Li J H; Ohnmacht C J; Smith R W; Trainor D A; Trivedi S; EMBASE Dihydropyridine K(ATP) potassium channel openers. Bioorganic Medicinal Chemistry Letters 3/1 (2725-2726) 1993

Edwards, Philip D.; Hesp, Barrie; Trainor, D. Amy; Willard, Alvin K. Enzymes as Targets for Drug Design in **Enzyme Chemistry**. Ed. Colin J. Suckling, Chapman & Hall, N.Y., 1990.

Takahashi, L. H.; Radhakrishman R.; Rosenfield, R. E. Jr.; Meyer E. F. Jr.; Trainor, D. A.; Crystal Structure of the Covalent Complex Formed by a Peptide Alpha Difluoro-Beta-Ketoamide with Porcine Pancreatic Elastase at 1.78-A Resolution. J. Am. Chem. Soc. 111 9 1989. 3368-3374

Takahashi, Lori H.; Radhakrishnan, R.; Rosenfield, Richard E.; Meyer, Edgar F.Jr.; Trainor, D. Amy; Stein, Mark. X-ray Diffraction Analysis of the Inhibition of Porcine Pancreatic Elastase (PPE) by a Peptidyl Trifluoromethyl Ketone. J. of Molecular Biology, 261, #2, 423-428 (1988).

Williams, J C; Stein R L; Knee C; Egan J; Falcone R; Trainor D A; Edwards P; Wolanin D; Wildonger R; Schwartz J; Hesp B; Giles R E; Krell R D; Pharmacologic Characterization of ICI200,880 - A novel potent and selective inhibitor of human neutrophil elastase. FASEB Journal, 1988

Trainor, D. Amy. Synthetic Inhibitors of Human Neutrophil Elastase. Trends Pharmacol. Sci., 8, #8, 303 (1987).

Stein, Ross L.; Strimpler, Ann M.; Viscarello, Barbara R.; Wildonger, Richard A.; Mauger, Russell C.; Trainor, D. Amy. Mechanism for slow-binding inhibition of human leukocyte elastase by valine-derived benzoxazinones. Biochemistry, 26, #13, 4126 (1987).

Trainor, DA; Synthetic inhibitors of human neutrophil elastase. Trends Pharmacol. Sci. 8/8 (303-307) 1987

Stein, Ross L.; Strimpler, Anne M.; Edwards, Phillip D.; Lewis, Joseph J.; Mauger, Russell C.; Schwartz, Jack A.; Stein, Mark M.; Trainor, D. Amy; Wildonger, Richard A.; Zottola, Mark A. Mechanism of slow-binding inhibition of human leukocyte elastase by trifluoromethyl ketones. Biochemistry, 26, #10, 2682 (1987).

Stein, Ross L.; Trainor, D. Amy. Mechanism of inactivation of human leukocyte elastase by a chloromethyl ketone: Kinetic and solvent isotope effect studies. Biochemistry, 25, #19, 5414 (1986).

Stein, R. L.; Trainor, D. A.; Wildonger, R. A. Neutrophil Elastase. Annu. Rep. Med. Chem., 20, 237 (1985).

DiNovi, Michael; Trainor, Diane A.; Nakanishi, Koji; Sanduja, Radhika; Alam, Maktoob. The structure of PB-1, an unusual toxin isolated from the red tide dinoflagellate ptychodiscus brevis. Tetrahedron Lett., 24, #9, 855 (1983).

Stonard, Richard J.; Trainor, Diane A.; Nakatani, Munehiro; Nakanishi, Koji. Additivity Relation in the amplitudes of exciton-split circular dichroism curves arising from interactions between different chromophores and its application in structural studies. J. Am. Chem. Soc., 105,#1, 130 (1983).

Cherbas, Peter; Trainor, Diane A.; Stonard, Richard J.; Nakanishi, Koji. 14-Deoxymuristerone, a compound exhibiting exceptional molting hormonal activity. J. Chem. Soc., Chem. Commun., #22, 1307 (1982).

Trainor, Diane A.; Parry, Ronald J.; Gitterman, Amy. Biotin biosynthesis. 2. Stereochemistry of sulfur introduction at C-4 of sethiobiotin. J. Am. Chem. Soc., 102, #4, 1467 (1980).

Parry, Ronald J.; Trainor, Diane Amy. Biosynthesis of lipoic acid. 2. Stereochemistry of sulfur introduction at C-6 of octanoic acid. J. Am. Chem. Soc., 100, #16, 5243 (1978).

PATENTS

Granted US Patents:

Acridinedione Therapeutic Agents
US 5484792 01/16/96

Antipsychotics
US 5719166 02/17/98
US 5399568 03/21/95
US 5550136 08/27/96

Difluoro Peptide Compounds
US 4873221 10/10/89

Difluoro Keto Compounds
US 4923890 05/08/1990

Heterocyclic Derivatives
US 5622964 04/22/97
US 5455253 10/03/95

Heterocyclic Ketones
US 5164371 11/17/92

Peptide Derivatives
US 5194588 03/16/93
US 4910190 03/20/1990
US 5055450 10/08/1991
US 4880780 11/14/1989

Piperidine Derivatives
US 5455246 10/03/95
US 5266570 11/30/93

Proline Derivatives - US 4596789 06/24/1986
US 4691007 09/01/1987

Propanamide Derivatives
&S 5482969 01/09/96

Trifluoromethyl Ketone Peptide Compounds
US 5726158 03/10/98
US 5414132 05/09/95

Urinary Incontinence
US 5340819 08/23/94

European Patent Applications

1. Novel Valyl Prolyl Valyl-Oxazoles and Benzoxazoles (and thio analogs) Which are Potent Elastase Inhibitors.
2. EPO 532 177 A1 - Methanoanthracenes as dopamine antagonists
3. EPO 532 178 A1 - Methanoanthracenes as dopamine antagonists
4. Three additional patents filed in the dopamine antagonist area and the potassium channel area

EXTERNAL PRESENTATIONS

ACS National Meeting - San Diego (1994) - Chair a symposium on K_{ATP} Channel Openers

23rd ACS Middle Atlantic Regional Meeting (1989) - Inhibition of Human Neutrophil Elastase (HNE) by Peptidyl Electrophilic Carbonyl Derivatives.

ACS National Meeting - New Orleans (1987) - Inhibition of Human Leukocyte Elastase Peptidyl Difluoromethylene Ketones

ACS Northeast Regional Meeting - Rochester (1987) - Peptide Fluorinated Ketone Inhibitors of HNE.

ACS National Meeting - Denver (1987) - Inhibition of Human Leukocyte Elastase by Peptide Trifluoromethyl Ketones

Gordon Research Conference in Medicinal Chemistry (1985) - Design of Novel Inhibitors of Human Leukocyte Elastase

University Talks

University of Minnesota
Purdue University
University of Kansas
Northwestern University
Lehigh University
University of Michigan
University of Pittsburgh

CURRICULUM VITAE

School of Electrical and Computer Engineering
University of Oklahoma

BIOGRAPHICAL

Name: **Bin Zheng**

Business Address: Stephenson Research & Technology Center, Suite 1001
University of Oklahoma
101 David L. Boren Blvd
Norman, OK 73019

Business Phone: 405-325-3597 **Business Fax:** 405-325-7066

E-mail Address: Bin.Zheng-1@ou.edu

Web Address: medical-imaging.rccc.ou.edu/zheng

EDUCATION and TRAINING

UNDERGRADUATE:

1978-1982	Shanghai University of Science and Technology Shanghai, China	Bachelor	Mechanical Engineering

GRADUATE:

1982-1984	Shanghai University of Science and Technology Shanghai, China	Master	Mechanical Engineering
1988-1993	University of Delaware Newark, DE, USA	PhD	Electrical Engineering

POSTGRADUATE:

1993-1994	Department of Radiology, University of Pittsburgh Pittsburgh, PA, USA.	Post-doctoral Fellow	Medical Imaging

---

APPOINTMENTS and POSITIONS

1984 – 1988	Department of Optical Instrumentation, Shanghai University of Science and Technology, Shanghai, China	Instructor
1988 – 1991	Department of Electrical Engineering, University of Delaware, Newark, DE, USA	Teaching Assistant
1991 – 1993	Department of Electrical Engineering, University of Delaware, Newark, DE, USA	Research Assistant
1993 – 1994	Imaging Research Division, Department of Radiology, University of Pittsburgh, Pittsburgh, PA, USA	Research Associate
1994 – 1997	Department of Radiology, University of Pittsburgh, Pittsburgh, PA, USA	Research Assistant Professor
1997 – 1998	Allegheny University of Health Sciences, Pittsburgh, PA, USA	Research Assistant Professor
1998 – 2002	Department of Radiology, University of Pittsburgh, Pittsburgh, PA, USA	Research Assistant Professor
2002 – 2009	Department of Radiology, University of Pittsburgh, Pittsburgh, PA, USA	Research Associate Professor
2009 – 2011	Department of Radiology, University of Pittsburgh, Pittsburgh, PA, USA	Research Professor
2012 – 2013	Department of Radiology, University of Pittsburgh, Pittsburgh, PA, USA	Professor of Radiology
2010 – 2013	Department of Bioengineering, University of Pittsburgh Pittsburgh, PA, USA	Adjunct Research Professor
2013 – Present	School of Electrical and Computer Engineering, University of Oklahoma, Norman, OK, USA	Professor
2013 – Present	Peggy and Charles Stephenson Cancer Center University of Oklahoma, Norman, OK, USA	Oklahoma TSET Cancer Research Scholar

---

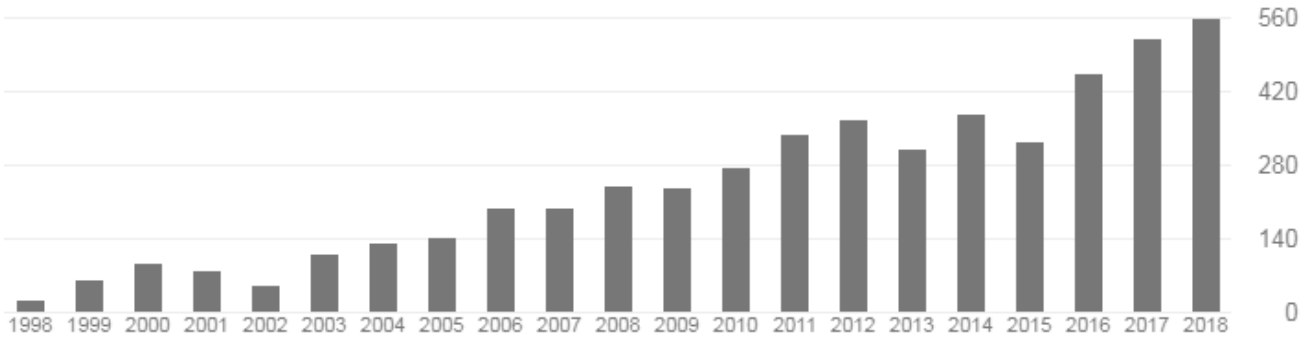
MEMBERSHIPS in PROFESSIONAL and SCIENTIFIC SOCIETIES

American Institute for Medicine and Biological Engineering (AIMBE)	Fellow
The International Society for Optical Engineering (SPIE)	Senior Member

---

PUBLICATIONS

Google Scholar	Citations	**5,181** (***ALL***)	2,543 (*Since 2013*)
	H – Index	**40**	25
	i10 – Index	**130**	88



Detailed and updated citation information can be found in:
https://scholar.google.com/citations?user=FnKrwz0AAAAJ&hl=en

I. Refereed Journal Articles

1. **Zheng B**, Ge Z. Improvement of focusing accuracy in the internal-focusing telescopic systems. *Journal of Shanghai Institute of Mechanical Engineering* 1983; 8:210-216 (Chinese).
2. **Zheng B**, Ge Z. A new method of long distant optical alignment. *Optical Instruments* 1985; 6:551-559 (Chinese).
3. Ge Z, **Zheng B**, Liu T. An automated method of monitoring inclination and vibration using a novel opto-electronic leveling instrument. *Optical Instruments* 1987; 8:389-396 (Chinese).
4. **Zheng B**, Pleass CM, Ih CS. Real-time characterization of motion of motile microorganisms by means of a hybrid laser Doppler velocimeter technique. *Optical Engineering* 1993; 32:2966-2973.
5. **Zheng B**, Pleass CM, Ih CS. Feature information extraction from dynamic bio-speckle. *Applied Optics* 1994; 33:231-237.
6. Chen J, **Zheng B**, Chang Y-H, Shaw CC, Towers JD, Gur D. Fractal analysis of trabecular patterns in projection radiographs: An assessment. *Investigative Radiology* 1994; 29:624-629.

7. **Zheng B**, Chang Y-H, Staiger M, Good W, Gur D. A method for computer-aided detection of clustered microcalcifications in digitized mammograms. *Academic Radiology* 1995; 2:655-662.
8. **Zheng B**, Chang Y-H, Gur D. Computerized detection of masses in digitized mammograms using single image segmentation and a multi-layer topographic feature analysis. *Academic Radiology* 1995; 2:959-966.
9. **Zheng B**, Chang Y-H, Gur D. Computerized detection of masses from digitized mammograms: A comparison of single image segmentation and bilateral image subtraction. *Academic Radiology* 1995; 2:1056-1061.
10. Chang Y-H, **Zheng B**, Gur D. Computerized identification of suspicious regions for masses in digitized mammograms. *Investigative Radiology* 1996; 31:146-153.
11. **Zheng B**, Chang Y-H, Gur D. An adaptive computer-aided diagnosis scheme of digitized mammograms. *Academic Radiology* 1996; 3:806-814.
12. Chang Y-H, **Zheng B**, Gur D. Robustness of computerized identification of masses in digitized mammograms: A preliminary assessment. *Investigative Radiology* 1996; 31:563-568.
13. **Zheng B**, Chang Y-H, Gur D. Mass detection in digitized mammograms using two independent computer-aided diagnosis schemes. *American Journal of Roentgenology* 1996; 167:1421-1424.
14. **Zheng B**, Chang Y-H, Gur D. On the reporting of mass contrast in CAD research. *Medical Physics* 1996; 23:2007-2009.
15. Chang Y-H, **Zheng B**, Gur D. Computer-aided detection of clustered microcalcifications in digitized mammograms: A robustness experiment. *Academic Radiology* 1997; 4:415-418.
16. **Zheng B**, Chang Y-H, Good WF, Gur D. Adequacy testing of variable domain coverage in CAD development. *Academic Radiology* 1997; 4:497-502.
17. Rymon R, **Zheng B**, Chang Y-H, Gur D. Incorporation of a set enumeration trees-based classifier into a hybrid computer-assisted diagnosis scheme for mass detection. *Academic Radiology* 1998; 5:181-187.
18. Chang Y-H, **Zheng B**, Good WF, Gur D. Identification of clustered microcalcifications on digitized mammograms using morphology and topology-based computer-aided detection schemes: A preliminary experiment. *Investigative Radiology* 1998; 33:746-751.
19. **Zheng B**, Chang Y-H, Wang X-H, Good WF, Gur D. Feature selection for computerized mass detection in digitized mammograms using a genetic algorithm. *Academic Radiology* 1999; 6:327-332.
20. Wang XH, **Zheng B**, Good WF, King JL, Chang YH. Computer-assisted diagnosis of breast cancer using a data-driven Bayesian belief network. *International Journal of Medical Informatics* 1999; 54:115-126.
21. Chang YH, Good WF, Sumkin JH, **Zheng B**, Gur D. Computerized localization of breast lesions from two views. An experimental comparison of two methods. *Investigative Radiology* 1999; 34:585-588.

22. **Zheng B**, Sumkin JH, Good WF, Maitz GS, Chang YH, Gur D. Applying computer-assisted detection schemes to digitized mammograms after JPEG data compression. *Academic Radiology* 2000; 7:595-602.

23. **Zheng B**, Ganott MA, Britton CA, Hakim CM, Hardesty LA, Chang TS, Gur D. Soft-copy mammographic readings with different computer-assisted diagnosis cuing environments: Preliminary findings. *Radiology* 2001; 221:633-640.

24. Chang YH, Hardesty LA, Hakim CM, Chang TS, **Zheng B**, Good WF, Gur D. Knowledge-based computer aided detection of masses on digitized mammograms: A preliminary assessment. *Medical Physics* 2001; 28:455-461.

25. **Zheng B**, Chang YH, Good WF, Gur D. Performance gain in computer-assisted detection schemes by averaging scores generated from artificial neural networks with adaptive filtering. *Medical Physics* 2001; 28:2302-2308.

26. **Zheng B,** Shah R, Wallace L, Hakim C, Ganott MA, Gur D. Computer-aided detection in mammography: An assessment of performance on current and prior images. *Academic Radiology* 2002; 9:1245-1250.

27. **Zheng B,** Good WF, Armfield DR, Cohen C, Hertzberg T, Sumkin JH, Gur D. Performance change of a mammographic CAD scheme optimized using most recent and prior image database. *Academic Radiology* 2003; 10:233-238.

28. Chang YH, Good WF, Leader JK, Wang XH, **Zheng B,** Hardesty LA, Hakim CM, Gur D. Integrated density of a lesion: A quantitative, mammographically derived, invariable measure. *Medical Physics* 2003; 30:1805-1811.

29. **Zheng B,** Hardesty LA, Poller WR, Sumkin J, Golla S. Computer-aided detection in mammography: A reproducibility assessment – initial experience. *Radiology* 2003; 228:58-62.

30. Leader JK, **Zheng B,** Rogers RM, Sciurba FC, Perez A, Chapman BE, Patel S, Fuhrman CR, Gur D. Automated lung segmentation in X-ray computed tomography: Development and evaluation of a heuristic threshold-based scheme. *Academic Radiology* 2003; 10: 1224-1236.

31. **Zheng B.** Long-term retention of mammographic computer-assisted diagnosis information is neither necessary nor desirable, *Radiology* 2004; 230:595-597.

32. **Zheng B,** Leader JK, Abrams G, Shindel B, Catullo V, Good WF, Gur D. Computer-aided detection schemes: The effect of limiting the number of cued regions in each case. *American Journal of Roentgenology* 2004; 182:579-583.

33. **Zheng B,** Swensson RG, Golla S, Hakim CM, Shah R, Wallace L, Gur D. Detection and classification performance levels of mammogaphic masses under different computer-aided detection cueing. *Academic Radiology* 2004; 11:398-406.

34. Gur D, **Zheng B,** Fuhrman CR, Hardesty LA. On the testing and reporting of computer-aided detection results for lung cancer detection. *Radiology* 2004; 232:5-6.

35. Leader JK, Rogers RM, Fuhrman CR, Sciurba FC, **Zheng B,** Thompson PF, Weissfeld JL, Golla SK, Gur D. Trachea size and morphology pre- and post-lung volume reduction surgery. *American Journal of Roentgenology* 2004; 183:315-321.

36. Gur D, Stalder J, Hardesty LA, **Zheng B,** Sumkin JH, Chough D, Shindel B, Rockette HE. CAD performance on sequentially ascertained mammographic examinations of masses: an assessment. *Radiology* 2004; 233:418-423.

37. **Zheng B,** Gur D, Good WF, Hardesty LA. A method to test the reproducibility and to improve performance of computer-aided detection schemes for digitized mammograms. *Medical Physics* 2004; 31:2964-2972.

38. **Zheng B,** Maitz GS, Ganott MA, Abrams G, Leader JK, Gur D. Performance and reproducibility of a computerized mass detection scheme for digitized mammography using rotated and re-sampled images – an assessment. *American Journal of Roentgenology* 2005; 185:194-198.

39. **Zheng B,** Chakraborty DP, Rockette HE, Maitz GS, Gur D. A comparison of two data analyses from two observer performance studies using jackknife ROC and JAFROC, *Medical Physics* 2005; 32:1031-1034.

40. Leader JK, Warfel TE, Fuhrman CR, Golla SK, Weissfeld JL, Avila RS, Turner WD, **Zheng B,** Pulmonary nodule detection with low-dose computed tomography of the lung: agreement among radiologists. *American Journal of Roentgenology* 2005; 185:973-978.

41. Wang X, **Zheng B,** Wood M, Li S, Chen W, Liu H, Development and evaluation of automated systems for detection and classification of banded chromosomes: Current status and future perspectives, *Journal of Physics. D: Applied Physics* 2005; 38:2536-2542.

42. **Zheng B,** Lu A, Hardesty LA, Sumkin JH, Hakim CM, Ganott MA, Gur D, A method to improve visual similarity of breast masses for an interactive computer-aided diagnosis environment. *Medical Physics* 2006; 33:111-117.

43. Wang X, Li S, Liu H, Mulvihill JJ, Chen W, **Zheng B**, A computer-aided method to expedite the evaluation of prognosis for childhood acute lymphoblastic leukemia, *Technology in Cancer Research and Treatment* 2006; 5:429-436.

44. **Zheng B,** Leader JK, Abrams GS, Lu AH, Wallace LP, Maitz GS, Gur D, Multiview based computer-aided detection scheme for breast masses, *Medical Physics* 2006; 33:3135-3143.

45. Gilbert S, **Zheng B,** Leader JK, Sciurba FC, Luketich JD, Furhman CR, Landreneau RJ, Gur D, Computerized estimation of lung volume removed during lung volume reduction surgery, *Academic Radiology* 2006; 13:1379-1386.

46. Yoon HJ, **Zheng B,** Sahiner B, Chakraborty DP, Evaluating computer aided detection algorithms, *Medical Physics* 2007; 34:2024-2038.

47. **Zheng B,** Leader JK, McMurray JM, Park SC, Fuhrman CR, Gur D, Sciurba FC, Automated detection and quantitative assessment of pulmonary airways depicted on CT images, *Medical Physics* 2007; 34:2844-2852.

48. **Zheng B,** Mello-Thoms C, Wang XH, Abrams GS, Sumkin JH, Chough DM, Ganott MA, Lu A, Gur D, Interactive computer aided diagnosis of breast masses: computerized selection of visually similar image sets from a reference library, *Academic Radiology* 2007; 14:917-927.

49. Park SC, Sukthankar R, Mummert L, Satyanarayanan M, **Zheng B,** Optimization of reference library used in content-based medical image retrieval scheme, *Medical Physics* 2007; 34:4331-4339.

50. Wang X, **Zheng B,** Li S, Mulvihill JJ, Liu H, A rule-based computer scheme for centromere identification and polarity assignment of metaphase chromosomes, *Computer Methods and Programs in Biomedicine* 2008; 89:33-42.

51. Pu J, **Zheng B,** Leader JK, Gur D, An ellipse-fitting based method for efficient registration of breast masses on two mammographic views, *Medical Physics* 2008; 35:487-494.

52. Wang X, Li S, Liu H, Wood M, Chen W, **Zheng B,** Automated identification of analyzable metaphase chromosomes depicted on microscopic digital images, *Journal of Biomedical Informatics* 2008; 41: 264-271.

53. **Zheng B,** Zuley M, Sumkin JH, Catullo V, Abrams G, Rathfon G, Chough D, Gruss M, Gur D, Detection of breast abnormalities using a prototype electrical impedance spectroscopy system: a preliminary study, *Medical Physics* 2008; 35:3041-3048.

54. Pu J, **Zheng B,** Leader JK, Wang X, Gur D, An automated CT based lung nodule detection scheme using geometric analysis of signed distance field, *Medical Physics* 2008; 35:3453-3461.

55. Jiang L, Song E, Xu X, Ma G, **Zheng B,** Automated detection of breast mass spiculation levels and evaluation of scheme performance, *Academic Radiology* 2008; 15:1534-1544.

56. Wang X, **Zheng B,** Li S, Mulvihill JJ, Liu H, Development and assessment of an integrated computer-aided detection scheme for digital microscopic images of metaphase chromosomes, *Journal of Electronic Imaging* 2008; 17:043008-1-9.

57. Wang XH, Park SC, **Zheng B,** Improving performance of content-based image retrieval schemes in searching for similar breast mass regions: an assessment, *Physics in Medicine and Biology* 2009; 54:949-961.

58. Park SC, Pu J, **Zheng B,** Improving performance of computer-aided detection scheme by combining results from two machine learning classifiers, *Academic Radiology* 2009; 16:266-274.

59. Wang X, **Zheng B,** Li S, Mulvihill JJ, Wood MC, Liu H, Automated classification of metaphase chromosomes: optimization of an adaptive computerized scheme, *Journal of Biomedical Informatics* 2009; 42:22-31.

60. Wang X, **Zheng B,** Li S, Zhang R, Mulvihill JJ, Chen W, Liu H, Automated detection and analysis of fluorescent in situ hybridization (FISH) signals depicted in interphase nuclei of pap-smear specimens, *Journal of Biomedical Optics* 2009; 14:021002-1-10.

61. Pu J, Leader JK, **Zheng B,** Knollmann F, Fuhrman C, Sciurba FC, Gur D, A computational geometry approach to automated pulmonary fissure segmentation in CT examinations, *IEEE Transactions on Medical Imaging* 2009; 28:710-719.

62. **Zheng B,** Computer-aided diagnosis in mammography using content-based image retrieval approaches: current status and future perspectives, *Algorithms* 2009; 2:828-849.

63. Bon JM, Leader JK, Weissfeld JL, Coxson HO, **Zheng B,** Branch RA, Kondragunta V, Lee JS, Zhang Y, Choi AM, Lokshin AE, Kaminski N, Gur D, Sciurba FC, The influence of Radiographic Phenotype and smoking status on peripheral blood biomarker patterns in chronic obstructive pulmonary disease, *PLoS One* 2009; 4(8):e6865.

64. Park SC, Wang XH, **Zheng B,** Assessment of performance improvement in content-based medical image retrieval schemes using fractal dimension, *Academic Radiology* 2009; 16:1171-1178.

65. **Zheng B,** Tan J, Ganott MA, Chough DM, Gur D, Matching breast masses depicted on different views: a comparison of three methods, *Academic Radiology* 2009; 16:1338-1347.

66. Pu J, **Zheng B,** Leader JK, Fuhrman C, Knollmann F, Gur D, Pulmonary lobe segmentation in CT examinations using implicit surface fitting, *IEEE Transactions on Medical Imaging* 2009; 28:1986-1996.

67. Yang L, Jin R, Mummert L, Sukthankar R, Goode A, **Zheng B,** Satyanarayanan M, A boosting framework for visuality-preserving distance metric learning and its application to medical image retrieval, *IEEE Transactions on Pattern Analysis and Machine Intelligence,* 2010; 32:30-44.

68. Wang X, Lederman D, Tan J, **Zheng B,** Computer-aided detection: The impact of machine learning classifier and image feature selection on scheme performance, *International Journal of Intelligent Information Processing* 2010; 1:30-40.

69. Wang X, **Zheng B**, Zhang RR, Li S, Mulvihill JJ, Lu X, Pang H, Liu H, Automated analysis of fluorescent in situ hybridization (FISH) labeled genetic biomarkers in assisting cervical cancer diagnosis, *Technology in Cancer Research and Treatment* 2010; 9:231-242.

70. Tan J, Pu J, **Zheng B,** Wang X, Leader JK, Computerized comprehensive data analysis of lung imaging database consortium (LIDC), *Medical Physics* 2010; 37:3802-3808.

71. Wang X, **Zheng B,** Li S, Mulvihill JJ, Liu H, Automated identification of abnormal metaphase chromosome cells for the detection of chronic myeloid leukemia using microscopic images, *Journal of Biomedical Optics* 2010; 15:046026-1-12.

72. Wang X, Lederman D, Tan J, Wang XH, **Zheng B,** Computerized detection of breast tissue asymmetry depicted on bilateral mammograms: a preliminary study of breast risk stratification, *Academic Radiology* 2010; 17:1234-1241.

73. **Zheng B,** Wang X, Lederman D, Tan J, Gur D, Computer-aided detection: The effect of training databases on detection of subtle breast masses, *Academic Radiology* 2010; 17:1401-1408.

74. **Zheng B,** Lederman D, Sumkin JH, Zuley ML, Gruss MZ, Levy LS, Gur D, A preliminary evaluation of multi-probe resonance-frequency electrical impedance based measures of breast, *Academic Radiology* 2011; 18:220-229.

75. Wang XH, Park SC, **Zheng B,** Assessment of performance and reliability of computer-aided detection scheme using content-based image retrieval approach and limited reference database, *Journal of Digital Imaging* 2011; 24:352-359.

76. Park SC, Chapman BE, **Zheng B,** A multi-stage approach to improve performance of computer-aided detection of pulmonary embolisms depicted on CT images: Preliminary investigation, *IEEE Transaction on Biomedical Engineering* 2011; 58:1519-1527.

77. Lederman D, **Zheng B,** Wang X, Wang XH, Gur D, Improving breast cancer risk stratification using resonance-frequency electrical impedance spectroscopy through fusion of multiple classifiers, *Annals of Biomedical Engineering*, 2011; 39:931-945.

78. Park SC, Tan J, Wang X, Lederman D, Leader JK, Kim SH, **Zheng B,** Computer-aided detection of early interstitial lung diseases using low-dose CT images, *Physics in Medicine and Biology* 2011; 56:1139-1153.

79. Lederman D, **Zheng B,** Wang X, Sumkin JH, Gur D, A GMM-based breast cancer risk stratification using a resonance-frequency electrical impedance spectroscopy, *Medical Physics* 2011; 38:1649-1659.

80. Park SC, Tan J, Leader JK, **Zheng B,** Separation of left and right lungs using 3D information of sequential CT images and a guided dynamic programming algorithm, *Journal of Computer Assisted Tomography* 2011; 35:280-289.

81. Chen X, **Zheng B,** Liu H, Optical and digital microscopic imaging techniques and applications in pathology, *Analytical Cellular Pathology* 2011; 34:5-18.

82. Yun S, Nie S, **Zheng B,** Improving accuracy of XRII image distortion correction using a new hybrid image processing method: Performance assessment, *Medical Physics* 2011; 38:5921-5932.

83. Wang X, Lederman D, Tan J, Wang XH, **Zheng B,** Computerized prediction of risk for developing breast cancer based on bilateral mammographic breast tissue asymmetry, *Medical Engineering & Physics* 2011; 33:934-942.

84. **Zheng B,** Sumkin JH, Zuley M, Lederman D, Wang X, Gur D, Computer-aided detection of breast masses depicted on full-field digital mammograms: a performance assessment, *British Journal of Radiology* 2012; 85:e153-161.

85. Wang X, Li L, Xu W, Liu W, Lederman D, **Zheng B**, Improving performance of computer-aided detection of subtle breast masses using an adaptive cueing method, *Physics in Medicine and Biology* 2012; 57:561-575.

86. Wang X, Li L, Xu W, Liu W, Lederman D, **Zheng B,** Improving Performance of Computer-Aided Detection of Masses by Incorporating Bilateral Mammographic Density Asymmetry: An Assessment, *Academic Radiology* 2012; 19:303-310.

87. Li Z, Li S, **Zheng B,** Zhang R, Li Y, Tian H, Chen W, Liu H, Potential clinical impact of 3-D visualization for fluorescent in situ hybridization (FISH) image analysis, *Journal of Biomedical Optics* 2012; 17:050501.

88. **Zheng B,** Sumkin JH, Zuley ML, Wang X, Klym AH, Gur D, Bilateral mammographic density asymmetry and breast cancer risk: A preliminary assessment, *European Journal of Radiology* 2012; 81:3222-3228.

89. Wang X, Li Y, Liu H, Li S, Zhang RR, **Zheng B,** Fluorescence in situ hybridization (FISH) signal analysis using automated generated projection images, *Analytical Cellular Pathology* 2012; 35:395-405.

90. Qiu Y, Cheng X, Li Y, **Zheng B,** Li S, Chen R, Liu H, The impact of the optical depth of field on cytogenetic image quality in scanning microscope, *Journal of Biomedical Optics* 2012; 17:96017.

91. Wang X, Li L, Liu W, Xu W, Lederman D, **Zheng B**, An interactive system for computer-aided diagnosis of breast masses, *Journal of Digital Imaging* 2012; 25:570-579.

92. Qiu Y, Li Y, Chen WR, **Zheng B,** Li S, Liu H, Evaluations of auto-focusing methods under a microscopic imaging modality: for the metaphase chromosome image analysis, *Analytical Cellular Pathology* 2013; 36:37-44.

93. **Zheng B,** Tublin ME, Klym AH, Gur D, Classification of thyroid nodules using a resonance-frequency based electrical impedance spectroscopy: A preliminary assessment, *Thyroid* 2013; 23:854-862.

94. Ren L, Li Z, Li Y, **Zheng B,** Li S, Chen X, Liu H, The impact of the condenser on cytogenetic image quality in digital microscope system, *Analytical Cellular Pathology* 2013; 36; 45-59.

95. Chen X, Ren L, **Zheng B,** Liu H, Physics and engineering aspects of cell and tissue imaging systems: microscopic devices and computer assisted diagnosis, *Studies in Health Technology and Informatics* 2013; 185:1-22.

96. Ramalingam P, **Zheng B,** Optimization of a computer-aided detection scheme using a logistic regression model and information gain feature selection method, *Global Journal of Breast Cancer Research* 2013; 1:1-7.

97. Li Z, Chen X, Ren L, Song J, Li Y, **Zheng B,** Liu H, Simultaneous dual-color fluorescence microscope: A characterization study, *Analytical Cellular Pathology* 2013; 36:163-172.

98. Petrick N, Sahiner B, Armato SG, Bert A, Correale L, Delsanto S, Freedman MT, Fryd D, Gur D, Hadjiiski L, Huo Z, Jiang Y, Morra L, Paquerault S, Raykar V, Samuelson F, Summers RM, Tourassi G, Yoshida H, **Zheng B,** Zhou C, Chan HP, Evaluation of computer-aided detection and diagnosis systems, *Medical Physics* 2013; 40:087001-1-17.

99. Tan M, **Zheng B,** Ramalingam P, Gur D, Prediction of near-term breast cancer risk based on bilateral mammographic feature asymmetry, *Academic Radiology* 2013; 20:1542-1550.

100. Yang Q, Li L, Zhang J, Shao G, **Zheng B,** A computerized image biomarker to assist diagnosis of breast cancer using breast magnetic resonance images: a preliminary assessment, *Journal of Digital Imaging* 2014; 27:152-160.

101. Gu S, Leader J, **Zheng B**, Sciurba F, Gur D, Pu, J, Direct assessment of lung function in COPD using CT densitometric measures, *Physiological Measurement* 2014; 35:833-845.

102. Sun W, **Zheng B,** Lure F, Wu T, Zhang J, Wang B, Saltzstein EC, Qian W, Prediction of near-term risk of developing breast cancer using computerized features from bilateral mammograms, *Computerized Medical Imaging and Graphics,* 2014; 38:348-357.

103. Ke ET, li L, Liu W, Xu W, Zhang L, **Zheng B,** Applying visual perception information for detection analysis and automatic extraction of breast mass in mammograms, Chinese Journal of Biomedical Engineering, 2014; 33:28-36.

104. **Zheng B,** Tan M, Ramalingam P, Gur D, Association between computed tissue asymmetry in bilateral mammograms and near-term breast cancer risk, *The Breast Journal* 2014; 20:249-257.

105. Tan M, Pu J, **Zheng B,** Optimization of breast mass classification using sequential forward floating selection (SFFS) and a support vector machine (SVM) model, *International Journal of Computer-assisted Radiology and Surgery*, 2014; 9:1005-1020.

106. Song J, **Zheng B,** Bu X, Fei Y, Shi S, Negative association of R-Ras activation and breast cancer development, Oncology Report, 2014; 31:2776-2784.

107. Yang Q, Li L, Zhang J, Shao G, **Zheng B,** A computerized global MR image feature analysis scheme to assist diagnosis of breast cancer: a preliminary assessment, *European Journal of Radiology* 2014; 83:1086-1091.

108. Tan M, Pu J, **Zheng B,** Reduction of false-positive recalls using a computerized mammographic image feature analysis scheme, *Physics in Medicine and Biology* 2014; 59:4357-4373.

109. Tan M, Pu J, **Zheng B,** A new and fast image feature selection method for the developing an optimal mammographic mass detection scheme, *Medical Physics* 2014; 41:081906-1-12.

110. Tan M, Pu J, **Zheng B,** Optimization of feature selection in computer-aided detection schemes using phased searching with NEAT in a Time-Scaled Framework, *Cancer Infomatics*, 2014; 13(S1):17-27.

111. Qiu Y, Song J, Lu X, Li Y, **Zheng B,** Li S, Liu H, Feature selection for the automated detection of metaphase chromosomes: Performance comparison using a receiver operating characteristic (ROC) method, *Analytic Cellular Pathology* 2014; 565392.

112. Zhen Y, Gu S, Meng X, Zhang X, **Zheng B,** Wang N, Pu J, Automated identification of retinal vessels using a multiscale directional contrast quantification (MDCQ) strategy, *Medical Physics* 2014; 41:092702-1-13.

113. Ren L, Wu D, Fajardo LL, Li Y, **Zheng B,** Liu H, Detection of posteriorly located breast tumors using gold nanoparticles: A breast-mimicking phantom study, *Journal of X-ray Science and Technology*, 2014; 22:785-796.

114. Ju J, Li R, Gu S, Leader JK, Wang X, Chen Y, **Zheng B,** Wu S, Gur D, Sciurba F, Pu J, Impact of emphysema heterogeneity on pulmonary function, *PLOS ONE* 2014; 9:e113320.

115. Yang Q, Li L, Zhang J, Shao G, **Zheng B,** A new quantitative image analysis method for improving breast cancer diagnosis using DCE-MRI examinations, *Medical Physics* 2015; 42:103-109.

116. Gu S, Li R, Leader JK, **Zheng B,** Bon J, Gur D, Sciurba F, Jin C, Pu J, Obesity and extent of emphysema depicted at CT, *Clinical Radiology* 2015; 70:e14-e19.

117. Tan M, Pu J, Cheng S, Liu H, **Zheng B,** Assessment of a four-view mammographic image feature based fusion model to predict near-term breast cancer risk, *Annals of Biomedical Engineering* 2015; 43:2416-2428.

118. Wu D, Yan A, Li Y, Wong MD, **Zheng B,** Wu X, Liu H, Characterization of a high-energy in-line phase contrast tomosynthesis prototype, *Medical Physics* 2015; 42:2404-2420.

119. Tan M, Qian W, Pu J, Liu H, **Zheng B,** A new approach to develop computer-aided detection schemes of digital mammograms, *Physics in Medicine and Biology* 2015; 60:4413-4427.

120. Sun W, Tseng T, Qian W, Zhang J, Saltzstein EC, **Zheng B,** Lure F, Yu H, Zhou S, Using multiscale texture and density features for near-term breast cancer risk analysis, *Medical Physics* 2015; 42:2853-2862.

121. Gundreddy RR, Tan M, Qiu Y, Cheng S, Liu H, **Zheng B,** Assessment of performance and reproducibility of applying a content-based image retrieval scheme for classification of breast lesions, *Medical Physics* 2015; 42:4241-4249.

122. Qian W, Sun W, **Zheng B,** Improving the efficacy of mammography screening: the potential and challenge of developing new computer-aided detection approaches, *Expert Review of Medical Devices,* 2015; 12:497-499.

123. Aghaei F, Tan M, Hollingsworth AB, Qian W, Liu H, **Zheng B,** Computer-aided breast MR image feature analysis for prediction of tumor response to chemotherapy, *Medical Physics* 2015; 42:6520-6528.

124. Tan M, Li Z, Qiu Y, McMeekin S, Thai T, Ding K, Moore K, Liu H, **Zheng B,** A new approach to evaluate drug treatment response of ovarian cancer patients based on deformable image registration, *IEEE Transactions on Medical Imaging*, 2016; 35:316-325.

125. Qiu Y, Tan M, McMeekin S, Thai T, Ding K, Moore K, Liu H, **Zheng B,** Early prediction of clinical benefit of treating ovarian cancer using quantitative CT image feature analysis, *Acta Radiologica* 2016; 57;1149-1155.

126. Ghani M, Zhou Z, Ren L, Wong M, Li Y, **Zheng B,** Yang K, Liu H, Investigation of spatial resolution characteristics of an in vivo microcomputed tomography system, *Nuclear Instruments and Methods in Physics Research A* 2016; 807:129-136.

127. Emaminejad N, Qian W, Guan Y, Tan M, Qiu Y, Liu H, **Zheng B**, Fusion of quantitative image features and genomic biomarkers to improve prognosis assessment of early stage lung cancer patients, *IEEE Transactions on Biomedical Engineering,* 2016; 63:1034-1043.

128. Tan M, **Zheng B,** Leader JK, Gur D, Association between changes in mammographic image features and risk for near-term breast cancer development, *IEEE Transactions on Medical Imaging,* 2016; 35:1719-1728.

129. Yan S, Qian W, Guan Y, **Zheng B,** Improving lung cancer prognosis assessment by incorporating synthetic minority oversampling technique and score fusion method, *Medical Physics* 2016; 43:2694-2703.

130. **Zheng B,** Applying quantitative medical image processing and feature analysis to assess near-term breast cancer risk, *Optical Instruments* 2016; 38:189-199.

131. Wang Y, Thai T, Moore K, Ding K, McMeekin S, Liu H, **Zheng B,** Quantitative measurement of adiposity using CT images to predict the benefit of bevacizumab-based chemotherapy in epithelial ovarian cancer patients, *Oncology Letter* 2016; 12:680-686.

132. Ren L, Ghani MU, Wu D, **Zheng B,** Chen Y, Yang K, Wu X, Liu H, The impact of spectral filtration on image quality in micro-CT system, *Journal of Applied Clinical Medical Physics* 2016; 17:5714.

133. Aghaei F, Tan M, Hollingsworth AB, **Zheng B,** Applying a new quantitative global breast MRI feature analysis scheme to assess tumor response to chemotherapy, *Journal of Magnetic Resonance Imaging,* 2016; 44:1099-1106.

134. Ren L, Wu D, Li Y, **Zheng B**, Chen Y, Yang K, Liu H, Practical alignment method for x-ray spectral measurement in micro-CT system based on 3D printing technology, *Biomedical Physics & Engineering Express*, 2016; 2:037004.

135. Wang Y, Qiu Y, Thai T, Moore K, Liu H, **Zheng B,** Applying a computer-aided scheme to detect a new radiographic image marker for prediction of chemotherapy outcome, *BMC Medical Imaging* 2016; 16:52.

136. Qiu Y, Lu X, Tan M, Li S, Liu H, **Zheng B,** Increasing the efficacy of detecting residual cancer cells using a whole-slide image scanning method and a computer-aided detection scheme, *Journal of Applied Biotechnology & Bioengineering* 2016; DOI:10.15406/jabb.2016.01.00001.

137. Gong J, Liu J, Wang L, **Zheng B,** Nie S, Computer-aided detection of pulmonary nodules using dynamic self-adaptive template matching and a FLDA classifier, *Physica Medica* 2016; 32:1502-1509.

138. Tan M, Aghaei F, Wang Y, **Zheng B**, Developing a new case based computer-aided detection scheme and an adaptive cueing method to improve performance in detecting mammographic lesions, *Physics in Medicine and Biology* 2017; 62:358-376.

139. Ghani M, Wong M, Ren L, Wu D, **Zheng B,** Rong JX, Wu X, Liu H, Characterization of continuous and pulsed emission modes of a hybrid micro focus x-ray source for medical imaging applications, *Nuclear Instruments and Methods in Physics Research A* 2017; 853:70-77.

140. Wang Y, Aghaei F, Zarafshani A, Qiu Y, Qian W, **Zheng B,** Computer-aided classification of mammographic masses using visually sensitive image features, *Journal of X-ray Science and technology* 2017; 25:171-186.

141. Fan M, Li H, Wang S, **Zheng B,** Zhang J, Li L, Radiomic analysis reveals DCE-MRI features for prediction of molecular subtypes of breast cancer, *PLoS One* 2017; 12(2):e0171683.

142. Ghani MU, Ren L, Wong M, Li Y, **Zheng B,** Rong XJ, Yang K, Liu H, Noise power characteristics of a micro-computed tomography system, *Journal of Computer Assisted Tomography* 2017; 41(1):82-89.

143. Zarafshani A, Dhurjaty S, Wang Y, Tang S, Xiang L, **Zheng B,** Feasibility test of quantitative assessment of breast density based on dielectric impedance spectroscopy, *Journal of Applied Biotechnology and Bioengineering,* 2017; 2:00047.

144. Wang Y, Qiu Y, Thai T, Moore K, Liu H, **Zheng B,** A two-step convolutional neural network based computer-aided detection scheme for automatically segmenting adipose tissue depicting on CT images, *Computer Methods and Programs in Biomedicine* 2017; 144:97-104.

145. Ghani MU, Wong MD, Wu D, **Zheng B,** Fajardo LL, Yan A, Fuh J, Wu X, Liu H, Detectability comparison between a high energy x-ray phase sensitive and mammography systems in imaging phantoms with varying glandular-adipose ratios, *Physics in Medicine and Biology* 2017; 62:3523-3538.

146. Tang S, Nguyen DH, Zarafshani A, Ramseyer C, **Zheng B,** Liu H, Xiang L, X-ray-induced acoustic computed tomography with an ultrasound transducer ring-array, *Applied Physics Letters* 2017; 110:103504.

147. Qiu Y, Yan S, Gundreddy R, Wang Y, Cheng S, Liu H, **Zheng B**, A new approach to develop computer-aided diagnosis scheme of breast mass classification using deep learning technology, *Journal of X-ray Science and Technology* 2017; 25:751-763.

148. Danala G, Thai T, Gunderson C, Moxley K, Moore K, Mannel R, Liu H, **Zheng B,** Y. Qiu, Applying quantitative CT image feature analysis to predict response of ovarian cancer patients to chemotherapy, *Academic Radiology* 2017; 24:1233-1239.

149. Yan S, Wang Y, Aghaei F, Qiu Y, **Zheng B,** Applying a new bilateral mammographic density segmentation method to improve accuracy of breast cancer risk prediction, *International Journal of Computer Assisted Radiology and Surgery,* 2017; 12; 1819-1828.

150. Sun W, **Zheng B,** Qian W, Automatic feature learning using multichannel ROI based on deep structured algorithms for computerized lung cancer diagnosis, *Computers in Biology and Medicine* 2017; 89:530-539.

151. Wu D, Wong MD, Li Y, Fajardo L, **Zheng B,** Wu X, Liu H, Quantitative investigation of edge enhancement in in-line phase contrast projections and tomosynthesis provided by distributing microbubbles on the interface between two tissues: a phantom study, *Physics in Medicine and Biology* 2017; 62:9357-9376.

152. Wu D, Wong MD. Yang K. Yan A. Li Y, Fajarto L, **Zheng B,** Wu X, Liu H, Using microbubble as contrast agent for high-energy X-ray In-line phase contrast imaging: demonstration and comparison study, *IEEE Transactions on Biomedical Engineering,* 2018; 65:1117-1123.

153. Yan S, Wang Y, Aghaei F, Qiu Y, **Zheng B,** Improving performance of breast cancer risk prediction by incorporating optical density image feature analysis: An assessment, *Academic Radiology* 2017; DOI:10.1016/j.acra.2017.08.007.

154. Li Y, Fan M, Cheng H, Zhang P, **Zheng B,** Li L, Assessment of global and local region-based bilateral mammographic feature asymmetry to predict short-term breast cancer risk. *Physics in Medicine and Biology,* 2018; 63:025004-1-13.

155. Sun W, Tseng T, Qian W, Saltzstein EC, **Zheng B,** Yu H, Zhou S, A new near-term breast cancer risk prediction scheme based on the quantitative analysis of ipsilateral view mammograms, *Computer Methods and Programs in Biomedicine*, 2018; 155:28-38.

156. Zarafshani A, Bach T, Chatwin CR, Tang S, Xiang L, **Zheng B,** Conditioning electrical impedance mammography system, *Measurement* 2018; 116:38-48.

157. Ren L, **Zheng B,** Liu H, Tutorial on X-ray photon counting detector characterization, *Journal of X-ray Science and Technology* 2018; 26:1-28.

158. Patel BK, Ranjbar S, Wu T, Pockaj BA, Li J, Zhang N, Lobes M, **Zheng B,** Mitchell JR, Computer-aided diagnosis of contrast-enhanced spectral mammography: A feasibility study, *European Journal of Radiology*, 2018; 98:207-213.

159. Heidari M, Khuzani A, Hollingsworth AB, Danala G, Mirniaharikandehei S, Qiu Y, Liu H, **Zheng B,** Prediction of breast cancer risk using a machine learning approach embedded with a locality preserving projection algorithm, *Physics in Medicine and Biology,* 2018; 63:035020.

160. Gong J, Liu J, Wang L, Sun X, Zheng B, Nie S, Automatic detection of pulmonary nodules in CT images by incorporating 3D tensor filtering with local image feature analysis, *Physica Medica* 2018; 46:124-133.

SMU

Office of the President

January 9, 2019

Mr. Wayne R. Roberts
Chief Executive Officer
Cancer Prevention & Research Institute of Texas
P.O. Box 12097
Austin, Texas 78711

Dear Mr. Roberts,

Thank you for your invitation to nominate a representative from SMU to serve as a member of the Cancer Prevention and Research Institute of Texas' (CPRIT) University Advisory Committee (UAC).

I nominate Dr. Steven C. Currall, Provost and Vice President of Academic Affairs, to represent SMU on the committee. Throughout Dr. Currall's career, he has served in several roles that uniquely qualify him to serve CPRIT and SMU well as a member of the UAC. Some of those roles include:

- Interim Vice Chair, Chair of the Governance Committee, and a member of the Executive Committee Board of Directors of BioHouston.
- Advisor to the University of Texas M.D. Anderson Cancer Center's Division of Diagnostic Imaging on leadership analysis of departmental administrators.
- Chair, Board of Directors, Ecosystem for Biophotonics Innovation (EBI), Center for Biophotonics Science and Technology, School of Medicine, UC Davis.
- Vice Chair and member of the Executive Committee of the Board of Directors of the University of California Global Health Institute.
- Board of Directors, California Life Sciences Association.

I have enclosed Dr. Currall's biography for your reference as well.

Thank you for your consideration of this nomination.

Best wishes,

R. Gerald Turner
President

Steven C. Currall

Steven C. Currall is Provost and Vice President for Academic Affairs at Southern Methodist University (SMU). As Provost, he oversees all aspects of academic activity at SMU including seven academic units: Cox School of Business, Dedman College of Humanities and Sciences, Dedman School of Law, Meadows School of the Arts, Lyle School of Engineering, Perkins School of Theology, and Simmons School of Education and Human Development, as well as Central University Libraries, the Office of Research and Graduate Studies, satellite campuses, and other academic programs. At SMU, Currall is the David B. Miller Endowed Professor and holds academic appointments in the Cox School of Business, Dedman College of Humanities and Sciences and the Lyle School of Engineering.

Previously, Currall was the Vice Chair of the Board of Directors and member of the Executive Committee for the 10-campus University of California system's Global Health Institute. He also served on the Boards of Directors of the San Francisco Bay Area Council and the California Life Sciences Association.

Currall worked at the University of California, Davis (UC Davis), where he served as Senior Advisor to the Chancellor for Strategic Projects and Initiatives, during which he co-chaired a campus-wide strategic visioning exercise to position UC Davis as the "University of the 21st Century." He also led planning for an additional campus in the Sacramento region. At UC Davis, Currall served as the Dean of the Graduate School of Management, leading the School to the highest MBA program ranking in its history. At University College London, he was the founding chair of the Department of Management Science and Innovation in the Faculty of Engineering Sciences, where he was also a Vice Dean. For 12 years, he served as a professor at Rice University and held the William and Stephanie Sick Professorship of Entrepreneurship in the George R. Brown School of Engineering. He founded the Rice Alliance for Technology and Entrepreneurship.

He has led seven centers/institutes, and held campus-wide service roles as Chair of the Task Force on Faculty Salary Equity, Chair of the Strategic Review of Human Resources, Chair of Board of Directors of the Ecosystem for Biophotonics Innovation, and Vice Chair of Chancellor's Blue Ribbon Committee on Research.

A psychological scientist, Currall has conducted research and taught for nearly three decades on organizational psychology topics such as innovation, emerging technologies, negotiation, and corporate governance. At the invitation of the U.S. President's Council of Advisors on Science and Technology, Currall was a member of the Nanotechnology Technical Advisory Group. He has been a grantee on $21,533,893 in external funding of which over 78% came from referred research grants from the National Science Foundation (NSF) and National Institutes of Health. Currall was lead author of a book on university-business-government collaboration entitled, *Organized Innovation: A Blueprint for Renewing America's Prosperity* (Oxford, 2014). Based on a study funded by the NSF, the book is the culmination of a 10-year research project on interdisciplinary research involving science, engineering, and medicine. He has served as a member of several editorial review boards such as Academy of Management Review, Academy of Management Journal, and Organization Science. He is a Fellow of the American Association for the Advancement of Science.

Currall has been a member of the boards of BioHouston, Leadership in Medicine, Inc., Nanotechnology Foundation of Texas, and Interferometrics, Inc., a venture-funded medical device start-up. He has been quoted over 600 times in publications such as the New York Times, Wall Street Journal, Washington Post, Financial Times, Business Week, British Broadcasting Corporation (BBC) television, and the Nightly Business Report on public television.

Provost Currall earned a Ph.D. from Cornell University, a M.Sc. from the London School of Economics and Political Science, and a B.A. (cum laude) from Baylor University.

Provost Currall is married to Cheyenne Currall, Ph.D., Vice President and Executive Advisor for Global Advancement at University of Texas Southwestern Medical Center.

February 2019 Oversight Committee
Internal Audit Status Report
As of January 31, 2019

Weaver and Tidwell, LLP (Weaver) is the outsourced internal auditor of the Cancer Prevention Research Institute of Texas (CPRIT). The Weaver engagement team is led by Alyssa Martin, Partner and Daniel Graves, Partner.

2019 Internal Audit Plan and Schedule

The table below reflects the activity to date Weaver has completed for the 2019 Internal Audit Plan.

NEW INTERNAL AUDITS		
Internal Audit	**Description**	**Timing**
State Reporting	Fieldwork for the State Reporting audit was completed and an exit meeting was held on January 16, 2019. We issued the report on January 25, 2019. The audit resulted in an overall assessment of "Strong" with two Low findings: • Tracking and communicating report deadlines to CPRIT personnel with responsibility for report completion • Documenting procedures over the expected processes for managing and monitoring state reporting requirements Follow-up procedures on the remediation of the findings will be included in the proposed audit plan for fiscal year 2020.	Complete
Budget and Planning	Fieldwork for the Budget and Planning audit was completed and an exit meeting was held on January 16, 2019. We issued the report on January 25, 2019. The audit resulted in an overall assessment of "Strong" with no findings.	Complete

FOLLOW-UP PROCEDURES		
Follow-Up	**Description**	**Timing**
SAO Performance Measures Follow-Up • 3 Findings	Fieldwork for these follow-up procedures was completed on December 5, 2018. The report was issued December 12, 2018. All three findings from the prior audit were remediated.	Compete

Information Security Follow-Up	Internal Audit will perform follow-up procedures on the open findings from the 2016 Internal Audit to ensure corrective action has been taken.	April 22, 2019 – May 3, 2019
Communications Follow-Up • 1 High Finding • 4 Moderate Findings	Internal Audit will perform follow-up procedures on the 5 open findings from the 2018 Internal Audit to ensure corrective action has been taken.	April 22, 2019 – May 3, 2019
Post-Award Grant Monitoring Follow-up • 1 Moderate Finding	Internal Audit will perform follow-up procedures on the 1 open finding from the 2018 Internal Audit to ensure corrective action has been taken.	February 18 – 22, 2019
Procurement and P-Cards Follow-up • 1 Moderate Finding	Internal Audit will perform follow-up procedures on the 1 open finding from the 2017 Internal Audit to ensure corrective action has been taken.	February 18 – 22, 2019

We have prepared a summary schedule of audits, their status and a summary of the findings by risk rating. The schedule maps out the internal audit and follow-up procedures performed, by year, the report date, report rating, and the findings by risk rating. The summary schedule is attached.

We have submitted the 2018 Annual Internal Audit Report, and the periodic internal audit reports to the State Auditor's Office, Legislative Budget Board, Governor's Office, and Sunset Commission, as required by the Texas Internal Auditing Act.

Alyssa G. Martin, CPA, MBA, Internal Auditor
Executive Partner
Weaver and Tidwell L.L.P

Cancer Prevention and Research Institute of Texas
Schedule of Audits, Status, and Findings Summary
As of January 31, 2019

					Open Findings				Closed Findings				Total Findings			
Audit	**Fiscal Year**	**Status/Timing**	**Report Date**	**Report Rating**	**High**	**Mod**	**Low**	**Total**	**High**	**Mod**	**Low**	**Total**	**High**	**Mod**	**Low**	**Total**
Fiscal Year 2015																
Grant Management	2015	Complete	July 27, 2015	Satisfactory	-	8	1	9	-	-	-	-	-	8	1	9
Expenditures Internal Audit	2015	Complete	August 24, 2015	Strong	-	-	2	2	-	-	-	-	-	-	2	2
2014 Governance and IT Follow-Up	2015	Complete	August 14, 2015	Satisfactory	-	-	-	9	-	-	-	7	-	1	1	2
2014 Grantee Monitoring Follow-Up	2015	Complete	July 31, 2015	Satisfactory	-	-	-	14	-	-	-	11	1	-	2	3
Fiscal Year 2015 Subtotal					**-**	**8**	**3**	**34**	**-**	**-**	**-**	**18**	**1**	**9**	**6**	**16**
Fiscal Year 2016																
Commodity and Service Contracts Internal Audit	2016	Complete	May 13, 2016	Satisfactory	-	3	2	5	-	-	-	-	-	3	2	5
Revenue Internal Audit	2016	Complete	July 8, 2016	Strong	-	-	2	2	-	-	-	-	-	-	2	2
Information Security Internal Audit	2016	Complete	August 3, 2016													
Cash Management Internal Audit	2016	Complete	August 12, 2016	Strong	-	1	-	1	-	-	-	-	-	1	-	1
2015 Grant Management Follow-Up	2016	Complete	June 9, 2016	Strong	-	8	1	9	-	8	1	9	-	-	-	-
2015 Information Technology Follow-Up	2016	Complete	N/A	N/A	-	1	1	2	-	1	1	2	-	-	-	-
Fiscal Year 2016 Subtotal					**-**	**13**	**6**	**19**	**-**	**9**	**2**	**11**	**-**	**4**	**4**	**8**
Fiscal Year 2017																
Training Program Internal Audit	2017	Complete	March 10, 2017	Strong	-	2	-	2	-	-	-	-	-	2	-	2
Internal Agency Compliance	2017	Complete	April 17, 2017	Strong	-	1	-	1	-	-	-	-	-	1	-	1
Pre-Award Grant Management	2017	Complete	May 30, 2017	Satisfactory	1	2	-	3	-	-	-	-	1	2	-	3
Procurement and P-Card Internal Audit	2017	Complete	August 4, 2017	Satisfactory	-	7	2	9	-	-	-	-	-	7	2	9
2016 Information Security Follow-Up	2017	Complete	May 30, 2017													
2016 Commodity and Service Contracts Follow-Up	2017	Complete	July 13, 2017	Strong	-	3	2	5	-	3	2	5	-	-	-	-
2016 Revenue Follow-Up	2017	Complete	July 8, 2017	Strong	-	-	2	2	-	-	2	2	-	-	-	-
2016 Cash Management Follow-Up	2017	Complete	July 13, 2017	Strong	-	1	-	1	-	1	-	1	-	-	-	-
Fiscal Year 2017 Subtotal					**1**	**16**	**6**	**23**	**-**	**4**	**4**	**8**	**1**	**12**	**2**	**15**
Fiscal Year 2018																
Post Award Grant Monitoring Internal Audit Grant Contracting Internal Audit	2018	Complete	February 1, 2018	Strong	-	1	-	1	-	-	-	-	-	1	-	1
Communication Internal Audit	2018	Complete	April 30, 2018	Satisfactory	1	4	-	5	-	-	-	-	1	4	-	5
State Reporting Internal Audit	2018	FY 2019	TBD	TBD	-	-	-	-	-	-	-	-	-	-	-	-
Information Technology Services Internal Audit	2018	FY 2019	TBD	TBD	-	-	-	-	-	-	-	-	-	-	-	-
2016 Information Security Follow-Up	2018	Complete	July 17, 2018													
2017 Training Program Follow-Up	2018	Complete	January 19, 2018	Strong	-	2	-	2	-	2	-	2	-	-	-	-
2017 Internal Agency Compliance Follow-Up	2018	Complete	January 19, 2018	Strong	-	1	-	1	-	1	-	1	-	-	-	-
2017 Pre-Award Grant Management Follow-Up	2018	Complete	April 24, 2018	Strong	1	2	-	3	1	2	-	3	-	-	-	-
2017 Procurement and P-Card Follow-Up	2018	Complete	April 30, 2018	Strong	-	7	2	9	-	6	2	8	-	1	-	1
Fiscal Year 2018 Subtotal					**2**	**17**	**2**	**21**	**1**	**11**	**2**	**14**	**1**	**6**	**-**	**7**
Fiscal Year 2019																
State Reporting Internal Audit	2019	December 2018	January 25, 2019	Strong	-	-	2	2	-	-	-	-	-	-	2	2
Budget and Planning	2019	December 2018	January 25, 2019	Strong	-	-	-	-	-	-	-	-	-	-	-	-
2017 SAO Performance Measures Follow-up	2019	November 2018	December 6, 2018	Strong	-	-	3	3	-	-	3	3	-	-	-	-
2016 Information Security Follow-Up	2019	April 2019	TBD													
2018 Communication Follow-Up	2019	April 2019	TBD	TBD	1	4	-	5	-	-	-	-	1	4	-	5
2018 Post Award Grant Monitoring Follow-Up	2019	February 2019	TBD	TBD	-	1	-	1	-	-	-	-	-	1	-	1
2018 Grant Contracting Follow-Up			TBD	TBD												
2017 Procurement and P-Card Follow-Up	2019	February 2019	TBD	TBD	-	7	2	9	-	6	2	8	-	1	-	1
Fiscal Year 2019 Subtotal					**1**	**12**	**7**	**20**	**-**	**6**	**5**	**11**	**1**	**6**	**2**	**9**

FISCAL YEAR 2019 SUMMARY

Audit	**Fiscal Year**	**Status/Timing**	**Report Date**	**Report Rating**	**Findings**				**Closed Findings**				**Total Open Findings**				**Timing of Follow-Up Procedures by IA**
					High	**Mod**	**Low**	**Total**	**High**	**Mod**	**Low**	**Total**	**High**	**Mod**	**Low**	**Total**	
State Reporting Internal Audit	2019	December 2018	January 25, 2019	Strong	-	-	2	2	-	-	-	-	-	-	2	2	**FY 2020**
Budget and Planning	2019	December 2018	January 25, 2019	Strong	-	-	-	-	-	-	-	-	-	-	-	-	
Post Award Grant Monitoring Internal Audit Grant Contracting Internal Audit	2018	February 2019	TBD	TBD	-	1	-	1	-	-	-	-	-	1	-	1	**February 2019**
Communication Internal Audit	2018	February 2019	TBD	TBD	1	4	-	5	-	-	-	-	1	4	-	5	**April 2019**
SAO Performance Measures	2017	November 2019	December 6, 2018	Strong	-	-	3	3		-	3	3	-	-	-	-	
Procurement and P-Cards	2017	February 2019	TBD	TBD	-	7	2	9	-	6	2	8	-	1	-	1	**February 2019**
Information Security Internal Audit	2016	February2019	TBD														**April 2019**
Total Findings For Internal Audit Follow-Up					**1**	**12**	**7**	**20**	**-**	**6**	**5**	**11**	**1**	**6**	**2**	**9**	

weaver

Cancer Prevention & Research Institute of Texas

IA #03-2019 Internal Audit Report over
Budget and Planning
Report Date: January 16, 2019
Issued: January 25, 2019

weaver
Assurance • Tax • Advisory

CONTENTS

The Oversight Committee
Cancer Prevention & Research Institute of Texas
1701 North Congress Avenue, Suite 6-127
Austin, Texas 78701

This report presents the results of the internal audit procedures performed for the Cancer Prevention and Research Institute of Texas (CPRIT) during the period December 3, 2018, through January 16, 2019, relating to the state reporting processes.

The objectives of the internal audit were to evaluate the design and effectiveness of CPRIT's budget and planning process. The objectives were organized as follows:

A. Determine whether internal controls over budget and planning processes are in place to ensure that consistent processes are implemented and designed effectively to address the risks within the associated sub-processes and to ensure effective operations.
B. Ensure that controls over critical budget and planning processes are operating effectively and according to authoritative guidance.

To accomplish these objectives, we conducted interviews with CPRIT personnel responsible for the budget and planning processes. We also reviewed documentation and performed specific testing procedures to assess controls. Procedures were performed at CPRIT's office and completed on January 16, 2018.

The following report summarizes the findings identified, risks to the organization, recommendations for improvement and management's responses.

Weaver and Tidwell, L.L.P.

WEAVER AND TIDWELL, L.L.P.

Austin, Texas
January 25, 2019

Cancer Prevention & Research Institute of Texas

IA #03-2019 Internal Audit Report over Budget and Planning
January 16, 2019
Issued: January 25, 2019

Background

The Texas budget process begins the year prior to each regular state legislative session held in odd-numbered years. The process begins with each state agency preparing a five-year strategic plan that lays the foundation for the preparation of a detailed legislative appropriations request (LAR) under the guidance of the Legislative Budget Board (LBB) and Governor's Office of Budget and Policy (GOBP). LARs are submitted to the LBB, GOBP, Comptroller's office, and several other legislative agencies by the end of August in even-numbered years. The LBB and GOBP are statutorily required to hold a hearing about each agency's budget request in order to develop budget recommendations for the next biennial general appropriations act. The LBB produces a draft biennial budget that is made available at the beginning of each legislative session. During the legislative session, both houses develop their own versions of the appropriations act. The differences between the two budgets are ironed out during a budget conference committee at the end of the legislative session. The Comptroller of Public Accounts must certify that there is sufficient revenue to cover the appropriations made by the legislature before the bill is forwarded to the Governor for signature, the final step in the budget process.

As part of the LAR preparation process, each state agency must complete a base reconciliation schedule in order to ensure that an agency and the LBB are in agreement on the base budget for the next biennium. This step enables reconciliation of each agency's original appropriations by method of finance and full-time-equivalent (FTE) positions to the final expenditures for the previous fiscal year, the estimated amounts for the current fiscal year, and the budgeted amounts for the upcoming fiscal year.

CPRIT's Chief Operating Officer (COO) is responsible for preparing the agency's strategic plan, base reconciliation, and LAR. Once the base reconciliation is finalized, the COO evaluates current budget items against forecasts of future needs particularly for the agency's largest expenses including service contracts and staff payroll and benefits to develop the LAR. The COO also reviews and updates assumptions of available general obligation bond revenue. The draft LAR is reviewed by the Chief Executive Officer (CEO) before it is presented to the Oversight Committee for approval prior to submission to the LBB and GOBP.

After a new biennial appropriations act is signed by the Governor, the Accountant must complete an appropriation allocation worksheet for each fiscal year of the new biennium in the Uniform Statewide Accounting System (USAS) based on the final biennial appropriations in the Automated Budget and Evaluation System of Texas (ABEST). The Office of the Comptroller of Public Accounts uses this information to set up CPRIT's annual operating budgets in USAS, the state's accounting system of record.

During each biennium, CPRIT monitors its operating budget through a monthly financial report that reflects a reconciliation of actual to budgeted expenditures. This report is produced by the Operations Specialist and reviewed by the COO. The monthly financial reports produced in the third month of each fiscal quarter are presented to the Oversight Committee at each of their public meetings and submitted to the LBB in compliance with the quarterly budget reporting requirement in the general appropriations act.

Cancer Prevention & Research Institute of Texas

IA #03-2019 Internal Audit Report over Budget and Planning
January 16, 2019
Issued: January 25, 2019

Audit Objective and Scope

The audit focused on the budget and planning processes at CPRIT. We reviewed procedures in place for appropriate risk coverage, compliance with state requirements, and compliance with CPRIT policies and procedures for the budget and planning processes, including preparation and submission. The scope included an evaluation of the processes currently in practice covering activities within the following key areas:

- Legislative Appropriations Request
- Budgeting and Planning Process
- Budget Monitoring
- Review and Adjustment

The scope of the audit did not include an evaluation of the processes in place for preparing and submitting the Agency Strategic Plan as those processes were included in prior internal audits.

Our procedures were designed to ensure relevant risks were covered and verify the following:

Legislative Appropriations Request
- Funding requests are appropriate for agency needs
- Headcount requests are appropriate for agency needs
- Requests are based on reasonable assumptions
- Requested amounts have adequate support to facilitate review
- Exceptional item requests have adequate support
- Authorized FTE positions are appropriately identified

Budgeting and Planning Process
- Categories of financing and corresponding estimates are reasonable
- Costs are appropriately identified
- Cost estimates are reasonable
- Budgeted amounts are appropriately classified
- Budgeted amounts are allocated to the appropriate period
- Budget aligns with historical experience
- Once approved, budgets align with appropriated amounts
- Access provisioned in ABEST is appropriate

Budget Monitoring
- Budget setup in ABEST is reviewed by authorized personnel
- Encumbrances and obligations are appropriately identified
- Encumbrances and obligations are appropriately classified and recorded in the correct period
- Authorized FTE positions are routinely tracked and monitored
- Budget variances are appropriately identified and analyzed

Review and Transfer
- Budget is periodically reviewed by executive management
- Appropriation transfer requests are reviewed by authorized personnel
- Appropriation transfer requests are submitted timely

Cancer Prevention & Research Institute of Texas

IA #03-2019 Internal Audit Report over Budget and Planning
January 16, 2019
Issued: January 25, 2019

The objectives of this internal audit were as follows:

A. Determine whether internal controls over budget and planning processes are in place to ensure that consistent processes are implemented and designed effectively to address the risks within the associated sub-processes and to ensure effective operations.
B. Ensure that controls over selected high-risk processes within budget and planning processes are operating effectively and according to authoritative guidance.

Our procedures included interviewing key personnel responsible for budgeting and planning to gain an understanding of the current processes in place, examining existing documentation, and evaluating the internal controls over the processes. We evaluated the existing policies, procedures, and processes in their current state. Our coverage period was from May 1, 2017, through November 30, 2018.

Executive Summary

Through our interviews, evaluation of internal control design and testing of transactions, we determined controls over budget and planning processes were in place to ensure that consistent processes are implemented and designed to effectively address the risks within budget and planning processes and sub-processes. Opportunities for improvement were identified through our interviews, evaluation of internal control design, and transactional testing. These observations include those items that are not considered to be non-compliance issues with documented CPRIT policies and procedures. These are considered process improvement observations and the intent of the recommendations are to strengthen current CPRIT processes and controls. These observations were provided to management separately.

A summary of our results, by audit objective, is provided in the table below. *See the Appendix for an overview of the Assessment and Risk Ratings*.

OVERALL ASSESSMENT	STRONG

SCOPE AREA	RESULT	RATING
Objective A: Determine whether internal controls over budget and planning processes are in place to ensure that consistent processes are implemented and designed effectively to address the risks within the associated sub-processes and to ensure effective operations.	We identified seven controls in place within the budget and planning processes and sub-processes to ensure that consistent processes are implemented and designed effectively to address the associated risks.	STRONG

Cancer Prevention & Research Institute of Texas

IA #03-2019 Internal Audit Report over Budget and Planning
January 16, 2019
Issued: January 25, 2019

SCOPE AREA	RESULT	RATING
Objective B: Ensure that controls over high-risk processes within budget and planning processes are operating effectively and according to authoritative guidance.	Controls appear to be in place over high-risk processes within the budget and planning processes and are operating effectively and according to authoritative guidance.	**STRONG**

Conclusion

Based on our evaluation, the budget and planning processes have procedures and controls in place to conduct effective management of the significant budget and planning processes at CPRIT. We recommend continued diligence in maintaining internal controls over the processes to ensure effective operations.

Detailed Procedures Performed, Findings, Recommendations and Management Response

Cancer Prevention & Research Institute of Texas

IA #03-2019 Internal Audit Report over Budget and Planning
January 16, 2019
Issued: January 25, 2019

Detailed Procedures Performed, Findings, Recommendations and Management Response

Our procedures included interviewing key personnel associated with budget and planning processes to gain an understanding of the current processes in place, examining existing documentation, and evaluating the internal controls over the processes. We evaluated the existing policies, procedures, and processes in their current state.

Objective A: Design of Internal Controls

Determine whether internal controls over budget and planning processes are in place to ensure that consistent processes are implemented and designed effectively to address the risks within the associated sub-processes and to ensure effective operations.

Procedures Performed: We conducted interviews of key personnel associated with budget and planning processes and examined existing documentation to gain an understanding of current state reporting processes. We documented understanding of the processes and identified internal controls over the following sub-processes:

- Legislative Appropriations Request
- Budget and Planning Process
- Budget Monitoring
- Review and Adjustment

We evaluated the controls identified against expected controls to determine whether the identified reoccurring budget and planning procedures and internal controls are sufficiently designed to mitigate the critical risks associated with the communication process. We identified any unacceptable risk exposures due to gaps in the existing control structure as well as opportunities to strengthen the effectiveness and efficiency of the existing procedures.

Results: We identified seven controls in place over the significant activities within the budget and planning processes. Internal controls over budget and planning processes were in place to ensure that consistent processes are implemented and designed effectively to address the risks within the associated sub-processes and to ensure effective operations.

Process Area	Control Coverage	Findings
Legislative Appropriations Request	1	
Budget and Planning Process	2	
Budget Monitoring	4	
Review and Adjustment	3	
Total	**10***	

***Duplicate Control:** The total number of identified controls is 7. However, based on their design, controls address risks in multiple processes. We have mapped the 7 unique controls to the processes in which they mitigate the risks within the processes

Objective B: Effectiveness of Internal Controls

Ensure that controls over critical communication processes are operating effectively and according to authoritative guidance.

1. **Procedures Performed:** We examined the Legislative Appropriations Request submitted for the 2020-2021 biennium and verified the following:

    - Funding requests are appropriate for agency needs and based on reasonable assumptions
    - Categories of financing and corresponding estimates are reasonable
    - Costs are appropriately identified and estimates are reasonable
    - Requested amounts including exceptional item requests have adequate support
    - Headcount requests are appropriate for agency needs based on accurate assumptions
    - Authorized FTE positions are appropriately identified

    Results: No findings identified.

2. **Procedures Performed:** For the 2018 and 2019 biennium, we examined the CPRIT appropriation schedules submitted to the Comptroller's Appropriations Control Officer for fiscal years 2018 and 2019 and verified the following:

    - Budgeted amounts are appropriately classified
    - Budgeted amounts are allocated to the appropriate period
    - Budgets align with historical experience
    - Budgets align with appropriated amounts
    - Budget setup in ABEST is reviewed by authorized personnel

    Results: No findings identified.

3. **Procedures Performed:** We reviewed the most recent list of CPRIT active users of the Legislative Budget Board's ABEST system and verified that the access provisioned in ABEST is appropriate.

   Results: No findings identified.

4. **Procedures Performed:** We randomly selected four out of 18 monthly financial reports from May 1, 2017, through November 30, 2018, and verified the following:

   - Budget variances were appropriately identified and analyzed
   - Budgets are periodically reviewed by executive management.

   In addition, for each of the selected monthly financial reports, we randomly selected 20 budget entries to perform testing procedures. The selected entries were classified as either expenditures, encumbrances, or obligations. For each selected budget entry, we verified encumbrances and obligations were appropriately:

   - Identified
   - Classified
   - Recorded in the correct period

   Results: No findings identified.

5. **Procedures Performed:** We randomly selected two quarterly FTE reports submitted by the Operations Manager from May 1, 2017, through November 30, 2018, and verified whether authorized FTE positions were routinely tracked and monitored.

   Results: No findings identified.

6. **Procedures Performed:** For the single appropriation transfer request submitted to the LBB during the period from May 1, 2017, through November 30, 2018, we examined supporting documentation and verified the request was reviewed by authorized personnel and submitted in a timely manner.

   Results: No findings identified.

Appendix

Cancer Prevention & Research Institute of Texas

IA #03-2019 Internal Audit Report over Budget and Planning
January 16, 2019
Issued: January 25, 2019

The appendix defines the approach and classifications utilized by Internal Audit to assess the residual risk of the area under review, the priority of the findings identified, and the overall assessment of the procedures performed.

Report Ratings

The report rating encompasses the entire scope of the engagement and expresses the aggregate impact of the exceptions identified during our test work on one or more of the following objectives:

- Operating or program objectives and goals conform with those of the agency
- Agency objectives and goals are being met
- The activity under review is functioning in a manner which ensures:
    - Reliability and integrity of financial and operational information
    - Effectiveness and efficiency of operations and programs
    - Safeguarding of assets
    - Compliance with laws, regulations, policies, procedures and contracts

The following ratings are used to articulate the overall magnitude of the impact on the established criteria:

Strong	The area under review meets the expected level. No high risk rated findings and only a few moderate or low findings were identified.
Satisfactory	The area under review does not consistently meet the expected level. Several findings were identified and require routine efforts to correct, but do not significantly impair the control environment.
Unsatisfactory	The area under review is weak and frequently falls below expected levels. Numerous findings were identified that require substantial effort to correct.

Cancer Prevention & Research Institute of Texas

IA #03-2019 Internal Audit Report over Budget and Planning
January 16, 2019
Issued: January 25, 2019

Risk Ratings

Residual risk is the risk derived from the environment after considering the mitigating effect of internal controls. The area under audit has been assessed from a residual risk level utilizing the following risk management classification system.

High

High risk findings have qualitative factors that include, but are not limited to:

- Events that threaten the agency's achievement of strategic objectives or continued existence
- Impact of the finding could be felt outside of the agency or beyond a single function or department
- Potential material impact to operations or the agency's finances
- Remediation requires significant involvement from senior agency management

.

Moderate

Moderate risk findings have qualitative factors that include, but are not limited to:

- Events that could threaten financial or operational objectives of the agency
- Impact could be felt outside of the agency or across more than one function of the agency
- Noticeable and possibly material impact to the operations or finances of the agency
- Remediation efforts that will require the direct involvement of functional leader(s)
- May require senior agency management to be updated

Low

Low risk findings have qualitative factors that include, but are not limited to:

- Events that do not directly threaten the agency's strategic priorities
- Impact is limited to a single function within the agency
- Minimal financial or operational impact to the agency
- Require functional leader(s) to be kept updated, or have other controls that help to mitigate the related risk

Cancer Prevention & Research Institute of Texas

IA #02-2019 Internal Audit Report over State Reporting
Report Date: January 16, 2019
Issued: January 25, 2019

weaver
Assurance • Tax • Advisory

CONTENTS

The Oversight Committee
Cancer Prevention & Research Institute of Texas
1701 North Congress Avenue, Suite 6-127
Austin, Texas 78701

This report presents the results of the internal audit procedures performed for the Cancer Prevention and Research Institute of Texas (CPRIT) during the period October 22, 2018, through January 16, 2019, relating to the state reporting processes.

The objectives of the internal audit were to evaluate the design and effectiveness of CPRIT's state reporting processes. The objectives were organized as follows:

A. Determine whether internal controls over state reporting processes are in place to ensure that consistent processes are implemented and designed effectively to address the risks within the associated sub-processes and to ensure effective operations.
B. Ensure that controls over critical state reporting processes are operating effectively and according to authoritative guidance.

To accomplish these objectives, we conducted interviews with CPRIT personnel responsible for the state reporting processes. We also reviewed documentation and performed specific testing to assess controls. Procedures were performed at CPRIT's office and completed on January 16, 2019.

The following report summarizes the findings identified, risks to the organization, recommendations for improvement and management's responses.

Weaver and Tidwell, L.L.P.

WEAVER AND TIDWELL, L.L.P.

Austin, Texas
January 25, 2019

Cancer Prevention & Research Institute of Texas

IA #02-2019 Internal Audit Report over State Reporting
January 16, 2019
Issued: January 25, 2019

Background

CPRIT is the state agency established to expedite innovation in academic and product development cancer research, and to enhance access to evidence-based innovation prevention programs throughout the state. As a state agency, CPRIT must periodically report on the agency's operational and financial activities to the Governor, Texas Legislature, and other state oversight agencies.

Each state or legislative agency with responsibility for a mandated report provides submission guidance that includes reporting requirements, deadlines, and submission methodology to report recipients through electronic notifications to all state agencies several weeks or months prior to report deadlines, on their website, or on their reporting platform.

CPRIT personnel with responsibility for the preparation and submission of the report track reporting deadlines. To prepare reports, they compile data available on CPRIT systems and from external agencies, such as the Health and Human Services Commission and Comptroller of Public Accounts, according to the requirements. All reports, whether prepared by line staff or a member of executive management, are reviewed by at least one other member of executive management prior to submission. Copies of all reports produced are retained on CPRIT's internal network and many are publicly available on the CPRIT website.

Audit Objective and Scope

The audit focused on the state reporting processes in place throughout CPRIT. We reviewed procedures in place for appropriate risk coverage, compliance with state requirements, and compliance with CPRIT policies and procedures for preparing and submitting statutorily required reports and ad hoc reports (including public information requests). The scope included an evaluation of the processes currently in practice covering the activities within the following key areas:

- Due Date Monitoring and Tracking
- Research and Analytical Support
- Preparation
- Review and Approval
- Submission and Retention

The scope of the audit did not include document management and retention processes, reports reviewed in prior internal audits, or reports that are audited by other auditors including:

- Legislative Appropriations Requests
- CPRIT Achievement Reports
- Quarterly Grantee Compliance Reports
- Texas Cancer Plan
- Quarterly Internal Audit Reports to the Oversight Committee
- Annual Financial Audit Report
- Contract Reports to the Legislative Budget Board (LBB)
- Vendor Performance Reports to the Texas Comptroller
- Annual Internal Audit Report

Our procedures were designed to ensure relevant risks were covered and verify the following:

Due Date Monitoring and Tracking
- Report deadlines are tracked and communicated to CPRIT personnel with responsibility for report completion
- Adequate planning is performed to complete reports by the required deadline
- Deadlines are monitored and reported to CPRIT management

Research and Analytical Support
- Data sources are validated and approved
- Data compiled, analyzed and reported is accurate and complete
- Analysis of information reported is reviewed and approved prior to report finalization

Preparation
- Report preparation is performed by appropriate personnel
- Reports are prepared according to authoritative criteria and requirements
- Development of reports follows established CPRIT timelines
- Personnel receive appropriate training to prepare reports

Review and Approval
- Reports are reviewed by appropriate personnel for completeness and accuracy
- Reports are approved by management prior to submission

Submission and Retention
- Reports are delivered to the required recipients by the established deadlines
- Reports are published in all required locations
- Copies of reports are retained and accessible by appropriate CPRIT personnel

The objectives of this internal audit were as follows:

A. Determine whether internal controls over state reporting processes are in place to ensure that consistent processes are implemented and designed effectively to address the risks within the associated sub-processes and to ensure effective operations.
B. Ensure that controls over selected high-risk processes within state reporting processes are operating effectively and according to authoritative guidance.

Our procedures included interviewing key personnel responsible for state reporting processes to gain an understanding of the current processes in place, examining existing documentation, and evaluating the internal controls over state reporting. We evaluated the existing policies, procedures, and processes in their current state. Our coverage period was from January 1, 2017, through August 31, 2018.

Cancer Prevention & Research Institute of Texas

IA #02-2019 Internal Audit Report over State Reporting
January 16, 2019
Issued: January 25, 2019

Executive Summary

Through our interviews, evaluation of internal control design and testing of transactions we identified two findings. The listing of findings include those items that have been identified and are considered to be non-compliance issues with documented CPRIT policies and procedures, with rules and regulations required by law, or where there is a lack of procedures or internal controls in place to cover risks to CPRIT. These issues could have significant financial or operational implications.

A summary of our results, by audit objective, is provided in the table below. *See the Appendix for an overview of the Assessment and Risk Ratings*.

OVERALL ASSESSMENT	STRONG

SCOPE AREA	RESULT	RATING
Objective A: Determine whether internal controls over state reporting processes are in place to ensure that consistent processes are implemented and designed effectively to address the risks within the associated sub-processes and to ensure effective operations.	We identified eight controls in place within state reporting processes. However, there are opportunities to strengthen the processes and control environment including: • Tracking and communicating report deadlines to CPRIT personnel with responsibility for report completion • Documenting procedures over the expected processes for managing and monitoring state reporting requirements	STRONG
Objective B: Ensure that controls over high-risk processes within state reporting processes are operating effectively and according to authoritative guidance.	Controls appear to be in place; however, all are not consistently executed. We identified the following opportunity for improvement: • Documented procedures on the expected processes for maintaining information, reporting progress, and review and approval by executive management	STRONG

Conclusion

Based on our evaluation, the state reporting function has procedures and controls in place to conduct effective management of the significant processes within CPRIT. However, we identified two opportunities to improve the effectiveness of the controls within the state reporting process.

Specifically, CPRIT should ensure report deadlines are tracked and communicated to CPRIT personnel with responsibility for report completion. CPRIT should also implement procedures for managing and monitoring state reporting requirements. The procedures should include the retention requirements of report information/data, internal monitoring of report status, and coordination of report approval between the designated report process owners and executive management.

Follow-up procedures will be performed in Fiscal Year 2020 to evaluate the effectiveness of remediation efforts implemented to address the findings identified.

Detailed Procedures Performed, Findings, Recommendations and Management Response

Cancer Prevention & Research Institute of Texas

IA #02-2019 Internal Audit Report over State Reporting
January 16, 2019
Issued: January 25, 2019

Detailed Procedures Performed, Findings, Recommendations and Management Response

Our procedures included interviewing key personnel who perform communications and information technology work to gain an understanding of the current processes in place, examining existing documentation, and evaluating the internal controls over the processes. We evaluated the existing policies, procedures, and processes in their current state.

Objective A: Design of Internal Controls

Determine whether internal controls over state reporting processes are in place to ensure that consistent processes are implemented and designed effectively to address the risks within the associated sub-processes and to ensure effective operations.

Procedures Performed: We conducted interviews of key personnel who perform communications and information technology work and examined existing documentation to gain an understanding of current state reporting processes. We documented understanding of the processes and identified internal controls over the following sub-processes:

- Due Date Monitoring and Tracking
- Research and Analytical Support
- Preparation
- Review and Approval
- Submission and Retention

We evaluated the controls identified against expected controls to determine whether the identified re-occurring state reporting procedures and internal controls are sufficiently designed to mitigate the critical risks associated with the state reporting processes. We identified any unacceptable risk exposures due to gaps in the existing control structure as well as opportunities to strengthen the effectiveness and efficiency of the existing procedures.

Results: We identified eight controls in place over the significant activities within the state reporting processes. We identified two findings where improvements in the processes can be made.

Cancer Prevention & Research Institute of Texas

IA #02-2019 Internal Audit Report over State Reporting
January 16, 2019
Issued: January 25, 2019

Process Area	Control Coverage	Findings / Observations
Due Date Monitoring and Tracking	1	**Finding 1**
Research and Analytical Support	2	
Preparation	2	**Finding 2**
Review and Approval	1	**Finding 2**
Submission and Retention	2	
Total	**8**	

Finding 1 – LOW – Report Deadline Tracking
CPRIT does not have an internal or centralized process for tracking all report deadlines and communicating report deadlines to CPRIT management. While some designated report process owners utilize tracking tools to monitor report deadlines, tracking is not consistently performed agency-wide.

We determined the FY 2017 Annual Report on Non-Financial Data and the FY 2017 Annual HUB Progress Report were not submitted by the due date.

In addition, we selected a sample of 20 out of 64 published state reports within our scope covering the period of January 1, 2017, through August 31, 2018. Based on the results of our testing, we identified the following:

- CPRIT does not have established tracking procedures for the Unexpended Balances notification, once it is determined that there are unexpended balances to report to the LBB. The due date of the report was monitored by the individual within CPRIT responsible for the notification to ensure it was completed by the required date
- Two Quarterly Financial Reports were submitted to the required recipients. However, CPRIT was unable to provide documentation to validate the timeliness of the submissions. The reports are submitted via interagency mail and evidence of submission was not documented or retained.

Recommendation: CPRIT should implement a process to monitor reporting requirements including report deadlines. This could include the use of a tracking tool such as a shared calendar or a schedule of reports that include the report due dates and the personnel responsible for preparing the report. The tracking tool could also be utilized for communicating the report responsibilities and deadlines to appropriate CPRIT personnel.

Management Response: CPRIT management agrees that there should be centralized tracking of state reporting deadlines. CPRIT will implement the use of a shared reporting calendar that the agency's executive assistant will maintain by entering each report deadline and sharing the appropriate deadline and reminders with the staff person responsible for the report for their calendar. The calendar will be used to monitor completion and submission of reports.

Responsible Party: Chief Operating Officer
Implementation Date: February 28, 2019

Finding 2 – LOW – Documented Policies and Procedures: CPRIT does not have documented procedures that identify the designated report process owners responsible for state reporting, outline CPRIT's expectations for managing reporting requirements, or explain the process for approving reports prior to submission. Although each state report has different requirements, CPRIT does not currently provide standard guidance to ensure report preparation is completed by the appropriate personnel and in accordance with authoritative criteria. Currently, CPRIT relies on experienced personnel to manage their assigned state reports which results in varying practices of monitoring reporting requirements and no established guidelines for documenting approval, submission, and retention of report information and data.

We selected a sample of 20 out of 64 published state reports within our scope covering the period of January 1, 2017, through August 31, 2018. Based on the results of our testing, we identified the following:

- Two HUB semi-annual reports included in our sample testing did not have any evidence of review and approval prior to report submission to ensure data and data sources were accurate and complete.

For HUB reporting, the Texas Comptroller of Public Accounts (CPA) provides a draft report to state agencies to review and verify the HUB data retrieved by the CPA from USAS is complete prior to the CPA publishing the final HUB Report. However, CPRIT does not have a formal process for subsequent review of the submission or evidence the review has been performed.

Recommendation: CPRIT should develop formalized and documented procedures on the expected processes for managing and monitoring state reporting requirements, including how to maintain information and data, report progress and status internally, and coordination efforts between designated process owners and executive management on approving state reports prior to submission.

Management Response: CPRIT management agrees that the procedures and responsibilities for completing required reports must be documented. The agency's policies and procedures will be updated to incorporate this information. The newly created shared reporting calendar will be used to monitor report status on a monthly basis.

Responsible Party: Chief Executive Officer, Chief Operating Officer, Operations Manager
Implementation Date: June 30, 2019

Objective B: Effectiveness of Internal Controls

Ensure that controls over critical communication processes are operating effectively and according to authoritative guidance.

1. **Procedures Performed:** We selected a sample of 20 out of 64 published state reports within our scope covering the period of January 1, 2017, through August 31, 2018. For each selected state report, we verified the following:

    - Reporting requirements including report deadlines are accurately tracked, monitored and communicated to responsible individuals
    - Data sources and data prepared for reports are validated for completeness and accuracy and appropriately reviewed
    - Report preparation follows established CPRIT's timelines
    - Where required, that personnel have appropriate training for preparing reports, such as public information requests
    - Reports are reviewed for completeness and accuracy and approvals are obtained prior to release
    - Reports are submitted to required recipients by established deadlines
    - Reports are published in all required locations, such as CPRIT's website
    - Reports are appropriately retained and accessible by appropriate personnel

Results: Based on the results of our testing, we have identified the following:

- Three state reports did not have formal tracking or monitoring of reporting requirements
- Two HUB semi-annual reports did not have evidence of review and approval prior to report submission to ensure data and data sources were accurate and complete
- Two Quarterly Financial Reports were submitted to the required recipients. However, CPRIT was unable to provide documentation to validate the timeliness of the submissions. The reports are submitted via interagency mail and evidence of submission was not documented or retained.

Finding 1 – LOW – Report Deadline Tracking

Finding 2 – LOW – Documented Policies and Procedures

Appendix

Cancer Prevention & Research Institute of Texas

IA #02-2019 Internal Audit Report over State Reporting
January 16, 2019
Issued: January 25, 2019

The appendix defines the approach and classifications utilized by Internal Audit to assess the residual risk of the area under review, the priority of the findings identified, and the overall assessment of the procedures performed.

Report Ratings

The report rating encompasses the entire scope of the engagement and expresses the aggregate impact of the exceptions identified during our test work on one or more of the following objectives:

- Operating or program objectives and goals conform with those of the agency
- Agency objectives and goals are being met
- The activity under review is functioning in a manner which ensures:
    - Reliability and integrity of financial and operational information
    - Effectiveness and efficiency of operations and programs
    - Safeguarding of assets
    - Compliance with laws, regulations, policies, procedures and contracts

The following ratings are used to articulate the overall magnitude of the impact on the established criteria:

Strong	The area under review meets the expected level. No high risk rated findings and only a few moderate or low findings were identified.
Satisfactory	The area under review does not consistently meet the expected level. Several findings were identified and require routine efforts to correct, but do not significantly impair the control environment.
Unsatisfactory	The area under review is weak and frequently falls below expected levels. Numerous findings were identified that require substantial effort to correct.

Cancer Prevention & Research Institute of Texas

IA #02-2019 Internal Audit Report over State Reporting
January 16, 2019
Issued: January 25, 2019

Risk Ratings

Residual risk is the risk derived from the environment after considering the mitigating effect of internal controls. The area under audit has been assessed from a residual risk level utilizing the following risk management classification system.

High

High risk findings have qualitative factors that include, but are not limited to:

- Events that threaten the agency's achievement of strategic objectives or continued existence
- Impact of the finding could be felt outside of the agency or beyond a single function or department
- Potential material impact to operations or the agency's finances
- Remediation requires significant involvement from senior agency management

.

Moderate

Moderate risk findings have qualitative factors that include, but are not limited to:

- Events that could threaten financial or operational objectives of the agency
- Impact could be felt outside of the agency or across more than one function of the agency
- Noticeable and possibly material impact to the operations or finances of the agency
- Remediation efforts that will require the direct involvement of functional leader(s)
- May require senior agency management to be updated

Low

Low risk findings have qualitative factors that include, but are not limited to:

- Events that do not directly threaten the agency's strategic priorities
- Impact is limited to a single function within the agency
- Minimal financial or operational impact to the agency
- Require functional leader(s) to be kept updated, or have other controls that help to mitigate the related risk

Cancer Prevention and Research Institute of Texas

IA #01-2019 Internal Audit Follow-Up Procedures Report over Performance Measures

Report Date: December 6, 2018

Issued: December 12, 2018

weaver

Assurance • Tax • Advisory

CONTENTS

The Oversight Committee
Cancer Prevention and Research Institute of Texas
1701 North Congress Avenue, Suite 6-127
Austin, TX 78701

This report presents the results of the internal audit follow-up procedures performed over Performance Measures for the Cancer Prevention and Research Institute of Texas (CPRIT). The follow-up was performed during the period October 22, 2018, through December 5, 2018, related to two areas for improvement from the State Auditor's Office's Audit Report on Performance Measures at the Cancer Prevention and Research Institute of Texas, dated December 2017.

The objective of these follow-up procedures was to validate that adequate corrective action has occurred in order to remediate the issues identified in the audit report.

To accomplish this objective, we conducted interviews and observations with key operations and compliance personnel. We also inspected documentation and performed specific testing procedures to validate actions taken. Procedures were performed at the Cancer Prevention and Research Institute of Texas office and were completed on December 5, 2018.

The following report summarizes conclusion of our procedures performed, recommendations for improvement and management's responses.

Weaver and Tidwell, L.L.P.

WEAVER AND TIDWELL, L.L.P.

Austin, Texas
December 12, 2018

Cancer Prevention and Research Institute of Texas

IA #01-2019 Internal Audit Follow-up Procedure Report Over
Performance Measures
December 6, 2018
Issued: December 12, 2018

Background

In 2017, the State Auditor's Office (SAO) conducted an audit over five key performance measures at the Cancer Prevention and Research Institute of Texas (CPRIT) and issued an audit report to the agency management. The audit report identified two areas for improvement related to controls over segregation of duties over data entry, as well as data collection and reporting.

The 2018 Internal Audit Plan included performing procedures to validate that CPRIT management has taken steps to address recommendations of the two areas of improvement.

Follow-Up Objective and Scope

The follow-up procedures focused on the remediation efforts taken by CPRIT management to address recommendations of the two areas of improvement included in the 2017 SAO Audit Report on Performance Measures at the Cancer Prevention and Research Institute of Texas and to validate that appropriate corrective action has been taken. The 2017 report identified the following two areas for improvement:

- Segregation of Duties
  - CPRIT should update its policies and procedures to ensure that an individual who is independent of the individual who enters data conducts and documents a review of performance measure data entry prior to releasing that data into Automated Budget and Evaluation System of Texas (ABEST).
  - CPRIT should implement controls that are effective in ensuring that grantees report accurate data for its performance measures.
- Data Collection and Reporting
  - CPRIT should establish controls to determine and document when entities meet a majority of grant criteria to become Texas-based before reporting them in its performance measures.
  - CPRIT should ensure that the method it uses to collect data for its performance measures produces reliable results.

Our follow-up procedures included verification of the following:

- CPRIT has updated its policies and procedures that ensure that an individual who is independent of the individual who enters data conducts and documents a review of performance measure data entry prior to releasing that data into ABEST.
- CPRIT has implemented controls that are effective in ensuring that grantees report accurate data for its performance measures.
- CPRIT has established controls to determine and document when entities meet a majority of grant criteria to become Texas-based before reporting them in its performance measures.
- The method used to collect data produces reliable results.

Our procedures included interviewing key personnel within key operations and compliance personnel, examining existing documentation and evaluating if corrective action has been taken. Our coverage period was from April 1, 2018, to October 31, 2018.

Cancer Prevention and Research Institute of Texas

IA #01-2019 Internal Audit Follow-up Procedure Report Over Performance Measures
December 6, 2018
Issued: December 12, 2018

Executive Summary

We validated that the two findings from the 2017 SAO Audit Report on Performance Measures at the Cancer Prevention and Research Institute of Texas were fully remediated.

The two findings included those items that were identified and are considered to be non-compliance issues with CPRIT's policies and procedures, rules and regulations required by law, or where there is a lack of procedures or internal controls in place to cover risks to CPRIT. These issues could have significant financial or operational implications.

A summary of our results by areas for improvement is provided in the table below. *See the Appendix for an overview of the Assessment.*

FOLLOW-UP ASSESSMENT	STRONG

SCOPE AREA	RESULT	Rating
Objective: Validate that adequate corrective action has occurred in order to remediate the issues identified in the 2017 SAO Audit Report on Performance Measures at the Cancer Prevention and Research institute of Texas.	We identified that procedures implemented by management adequately addressed and remediate the prior open findings..	**STRONG**

Conclusion

Based on our evaluation, CPRIT management has made satisfactory effort to remediate the findings from the 2017 SAO Audit Report on Performance Measures at the Cancer Prevention and Research institute of Texas. We recommend continued diligence in maintaining internal controls over performance measure reporting processes.

Detailed Follow-Up Results

Cancer Prevention and Research Institute of Texas

IA #01-2019 Internal Audit Follow-Up Procedures Report over Performance Measures
December 6, 2018
Issued: December 12, 2018

Detailed Follow-Up Results

Our procedures included interviewing key personnel in operations and compliance to gain an understanding of the corrective actions taken in order to address the two areas for improvement identified in the 2017 SAO Audit Report on Performance Measures at the Cancer Prevention and Research Institute of Texas, as well as examining existing documentation and communications, and performing testing in order to validate those corrective actions. We evaluated the existing policies, procedures, and processes in their current state.

Objective: Validate Remediation

Validate that adequate corrective action has occurred in order to remediate the issues identified in the 2017 SAO Audit Report on Performance Measures at the Cancer Prevention and Research institute of Texas.

Finding 1 – Segregation of Duties - CPRIT did not have documented policies related to or adequate segregation of duties between the entry and release of performance measure data into the Automated Budget and Evaluation System of Texas (ABEST). In addition, it did not perform independent reviews of performance measure data before entering that data into ABEST.

Also, an application control in the Institute's CPRIT Grant Management System (CGMS) related to grantee input and approval of progress reports was not adequately designed to prevent grantees from having the same individual both enter and release the information in a progress report. Because the Institute relies on the control described above to help ensure that grantees report accurate information, it may be relying on information that has not been properly reviewed at the grantee level to report its performance measures.

SAO Recommendation:

- CPRIT should update its policies and procedures to ensure that an individual who is independent of the individual who enters data conducts and documents a review of performance measure data entry prior to releasing that data into ABEST.
- CPRIT should implement controls that are effective in ensuring that grantees report accurate data for its performance measures.

Procedures Performed: We verified that CPRIT has documented procedures requiring the review and approval of data reported in ABEST as well as the segregation of duties between the entry and release of performance measure data into ABEST. Additionally, we verified that the data included in the performance measure reports was reviewed and approved by management prior to submission for Q3 and Q4 reports for fiscal year 2018.

We also verified that CPRIT's Compliance Program has incorporated procedures into their Onsite Review Checklist to verify that grantees have established appropriate segregation of duties for progress reporting in CGMS. Of the 32 onsite reviews that were performed from September 1, 2017, through October 31, 2018, we selected a sample of 7 that were performed after April 1, 2018. We verified that segregation of duties was inspected by CPRIT compliance staff during those onsite reviews.

Results: **Finding remediated**

Finding 2 – Data Collection and Reporting - Institute policy requires that entities meet a majority of the seven criteria to be reported for the Number of Entities Relocating to Texas for Cancer Research Related Projects performance measure. However, the Institute did not obtain documentation to show that entities met those criteria. Therefore, auditors were unable to determine whether the entities the Institute included in the number reported in that performance measure met a majority of the criteria listed above for being considered Texas based.

Additionally, the Institute double counted jobs held by Texans in reporting that performance measure to ABEST, leading to an overstatement of 24.2 percent of the number of jobs that the Institute reported in ABEST.

SAO Recommendation:

- CPRIT should establish controls to determine and document when entities meet a majority of grant criteria to become Texas-based before reporting them in its performance measures.
- CPRIT should ensure that the method it uses to collect data for its performance measures produces reliable results.

Procedures Performed: We verified that as part of the grantee's Annual Attestations, CPRIT's Compliance Program has incorporated specific reporting requirements for grantees to report compliance with at least 4 of the 7 criteria to be considered a Texas-based entity. Of the 55 active grantees, we selected a sample of 9 product development grantees and verified that these grantees have reported compliance with at least 4 of the 7 Texas-based criteria.

We also verified that the Compliance Program's trainings provided to grantees have included Texas location criteria and reporting requirements as a training topic for new Product Development Research grantees.

Additionally, we verified that the query used to compile the information to report the number of jobs was corrected by the grant management support services vendor. We obtained the detailed support for the grants and recalculated the number of jobs created and maintained for Q4 of fiscal year 2018 to verify that the calculations in the query were accurate.

We verified that CPRIT corrected the performance measure of number of new jobs created and maintained for the Q4 report submitted into ABEST for fiscal year 2018. We also verified that CPRIT management reviewed and verified the data included in the performance measure report prior to submission.

Results: **Finding remediated**

Appendix

Cancer Prevention and Research Institute of Texas

IA #01-2019 Internal Audit Follow-Up Procedures Report over Performance Measures
December 6, 2018
Issued: December 12, 2018

The appendix defines the approach and classifications utilized by Internal Audit regarding the overall assessment of the procedures performed.

Report Ratings

The report rating encompasses the entire scope of the engagement and expresses the aggregate impact of the exceptions identified during our test work on one or more of the following objectives:

- Operating or program objectives and goals conform with those of the agency
- Agency objectives and goals are being met
- The activity under review is functioning in a manner which ensures:
    - Reliability and integrity of financial and operational information
    - Effectiveness and efficiency of operations and programs
    - Safeguarding of assets
    - Compliance with laws, regulations, policies, procedures and contracts

The following ratings are used to articulate the overall magnitude of the impact on the established criteria:

Strong	The area under review meets the expected level. No high risk rated findings and only a few moderate or low findings were identified.
Satisfactory	The area under review does not consistently meet the expected level. Several findings were identified and require routine efforts to correct, but do not significantly impair the control environment.
Unsatisfactory	The area under review is weak and frequently falls below expected levels. Numerous findings were identified that require substantial effort to correct.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	KRISTEN PAULING DOYLE, GENERAL COUNSEL CAMERON L. ECKEL, STAFF ATTORNEY
SUBJECT:	CHAPTER 703 RULE CHANGES PROPOSED FOR FINAL ADOPTION
DATE:	FEBRUARY 8, 2019

Summary and Recommendation

The Board Governance Subcommittee recommends that the Oversight Committee adopt the proposed administrative rule changes to Chapter 703 as originally considered at the November meeting. Once the Oversight Committee approves the final order adopting the rule changes, CPRIT will submit the amendments to the Secretary of State and the changes will be effective 20 days later.

Discussion

State law requires an agency to set policy using a rulemaking process, which includes an opportunity for public comment on proposed rules and rule changes before the agency formally adopts the policy.

The Oversight Committee approved publication of the following proposed rule amendments to §§ 703.3, 703.13, 703.21, and 703.22 at the November meeting.

- The proposed amendment to §703.3(k) provides the process for a product development research grant applicant to receive a refund of the application fee if CPRIT removes the applicant's proposal from the review process prior to an evaluation by peer reviewers. CPRIT charges an application review fee to offset the increased review costs associated with the product development grant review. Occasionally, CPRIT withdraws a product development grant application from consideration before the initiating the peer review process, either at the request of the applicant or because the application is administratively noncompliant. Returning the application fee is equitable when the application does not begin the extensive peer review process. The new provision, §703.3(k)(4), establishes a process for the applicant to request the fee refund.

PO Box 12097 | Austin, Texas 78711 | PH: 512-463-3190 | F: 512-475-2563 | cprit.texas.gov

- The changes to § 703.13(b)(2) and (b)(2)(B) clarify that grantees must submit the required audit no later than nine months following the close of the grantee's fiscal year. Currently, § 703.13(b) sets the deadline at 270 days because CPRIT's grant management system tracks deadlines in terms of days, not months. However, grantees are more familiar with tracking deadlines by month. As a result, a grantee may inadvertently file the audit report one or two days past the 270-day deadline, even though the report is filed within the nine-month period.

- The proposed amendment, § 703.21(b)(3)(k), sets September 1 as the initial reporting period for prevention grants approved for an award during the last quarter of the state fiscal year. CPRIT requires prevention grant recipients to submit quarterly reports. The grant contract effective date for all grants approved for awards during the last quarter of the fiscal year is August 31. Because the contract effective date drives the reporting period, these prevention grants have a one-day reporting period (August 31). Not only is little meaningful information gained from a one-day report, but some grantees inadvertently overlook the one-day report and become noncompliant. Clarifying that these grantees should report on the full quarter beginning September 1 addresses these issues.

- The proposed amendment to § 703.22(c) changes the deadline for grant recipients to complete annual compliance training from November 1 to December 31. The change correlates the annual requirement to the calendar year.

The Board Governance Subcommittee met on February 7th to review the final order with CPRIT's General Counsel. The Subcommittee recommends the Oversight Committee approve the final order adopting the proposed rule changes.

Next Steps

After the Oversight Committee adopts the proposed rule changes, CPRIT will submit the final order to the Secretary of State. The rule changes become effective 20 days after the date CPRIT files the order with the Secretary of State.

The Cancer Prevention and Research Institute of Texas ("CPRIT" or "the Institute") adopts the amendments to §§703.3, 703.13, 703.21, and 703.22 without changes to the proposed amendments as published in the January 4, 2019, issue of the Texas Register (44 TexReg 53), therefore, the rules will not be republished. The amendments clarify the processes, annual training and audit deadlines, and reporting periods for Institute grant recipients.

Reasoned Justification

The proposed amendment to §703.3 provides the process for a product development research grant applicant to receive a refund of the application fee if the CPRIT or the grant applicant withdraws the proposal from the review process prior to an evaluation by peer reviewers. The changes to § 703.13 clarify the deadline for grantees to submit the required audit report, revising the deadline from 270 days to nine months after the close of the grantee's fiscal year. The proposed amendment to § 703.21 sets the initial reporting period for prevention grants approved for an award during the last quarter of the state fiscal year. The proposed change allows prevention grantees to report on a full initial quarter. The proposed amendment to § 703.22 changes the deadline for grant recipients to complete annual compliance training from November 1 to December 31. The change correlates the annual requirement to the calendar year.

Summary of Public Comments and Staff Recommendation

CPRIT received no public comments regarding the proposed amendments to §§703.3, 703.13, 703.21, and 703.22.

The rule change is adopted under the authority of the Texas Health and Safety Code Annotated, § 102.108, which provides the Institute with broad rule-making authority to administer the chapter, including rules for awarding grants.

Certification

The Institute hereby certifies that Kristen Pauling Doyle, General Counsel, reviewed the adoption of the rules and found it to be a valid exercise of the agency's legal authority.

To be filed with the Office of Secretary of State on February 22, 2019.

<rule>

§703.3.Grant Applications.

(a) The Institute shall accept Grant Applications for Cancer Research and Cancer Prevention programs to be funded by the Cancer Prevention and Research Fund or the proceeds of general obligation bonds issued on behalf of the Institute in response to standard format Requests for Applications issued by the Institute.

(b) Each Request for Applications shall be publicly available through the Institute's Internet website. The Institute reserves the right to modify the format and content requirements for the

Requests for Applications from time to time. Notice of modifications will be announced and available through the Institute's Internet website. The Request for Applications shall:

(1) Include guidelines for the proposed projects and may be accompanied by instructions provided by the Institute.

(2) State the criteria to be used during the Grant Review Process to evaluate the merit of the Grant Application, including guidance regarding the range of possible scores.

(A) The specific criteria and scoring guidance shall be developed by the Chief Program Officer in consultation with the Review Council.

(B) When the Institute will use a preliminary evaluation process as described in §703.6 of this chapter (relating to Grant Review Process) for the Grant Applications submitted pursuant to a particular Grant Mechanism, the Request for Applications shall state the criteria and Grant Application components to be included in the preliminary evaluation.

(3) Specify limits, if any, on the number of Grant Applications that may be submitted by an entity for a particular Grant Mechanism to ensure timely and high-quality review when a large number of Grant Applications are anticipated.

(c) Requests for Applications for Cancer Research and Cancer Prevention projects issued by the Institute may address, but are not limited to, the following areas:

(1) Basic research;

(2) Translational research, including proof of concept, preclinical, and Product Development activities;

(3) Clinical research;

(4) Population based research;

(5) Training;

(6) Recruitment to the state of researchers and clinicians with innovative Cancer Research approaches;

(7) Infrastructure, including centers, core facilities, and shared instrumentation;

(8) Implementation of the Texas Cancer Plan; and

(9) Evidence based Cancer Prevention education, outreach, and training, and clinical programs and services.

(d) An otherwise qualified applicant is eligible solely for the Grant Mechanism specified by the Request for Applications under which the Grant Application was submitted.

(e) The Institute may limit the number of times a Grant Application not recommended for a Grant Award during a previous Grant Review Cycle may be resubmitted in a subsequent Grant Review Cycle. The Request for Applications will state the resubmission guidelines, including specific instructions for resubmissions.

(f) Failure to comply with the material and substantive requirements set forth in the Request for Applications may serve as grounds for disqualification from further consideration of the Grant Application by the Institute. A Grant Application determined by the Institute to be incomplete or otherwise noncompliant with the terms or instructions set forth by the Request for Applications shall not be eligible for consideration of a Grant Award.

(g) Only those Grant Applications submitted via the designated electronic portal designated by the Institute by the deadline, if any, stated in the Request for Applications shall be eligible for consideration of a Grant Award.

(1) Nothing herein shall prohibit the Institute from extending the submission deadline for one or more Grant Applications upon a showing of good cause, as determined by the Chief Program Officer.

(2) A request to extend the Grant Application submission deadline must be in writing and sent to the CPRIT Helpdesk via electronic mail, within 24 hours of the submission deadline.

(3) The Institute shall document any deadline extension granted, including the good cause for extending the deadline and will cause the documentation to be maintained as part of the Grant Review Process records.

(h) The Grant Applicant shall certify that it has not made and will not make a donation to the Institute or any foundation created to benefit the Institute.

(1) Grant Applicants that make a donation to the Institute or any foundation created to benefit the Institute on or after June 14, 2013, are ineligible to be considered for a Grant Award.

(2) For purposes of the required certification, the Grant Applicant includes the following individuals or the spouse or dependent child(ren) of the following individuals:

(A) the Principal Investigator, Program Director, or Company Representative;

(B) a Senior Member or Key Personnel listed on the Grant Application; and

(C) an officer or director of the Grant Applicant.

(3) Notwithstanding the foregoing, one or more donations exceeding $500 by an employee of a Grant Applicant not described by paragraph (2) of this subsection shall be considered to be made on behalf of the Grant Applicant for purposes of the certification.

(4) The certification shall be made at the time the Grant Application is submitted.

(5) The Chief Compliance Officer shall compare the list of Grant Applicants to a current list of donors to the Institute and any foundation created to benefit the Institute.

(6) To the extent that the Chief Compliance Officer has reason to believe that a Grant Applicant has made a donation to the Institute or any foundation created to benefit the Institute, the Chief Compliance Officer shall seek information from the Grant Applicant to resolve any issue. The Grant Application may continue in the Grant Review Process during the time the additional information is sought and under review by the Institute.

(7) If the Chief Compliance Officer determines that the Grant Applicant has made a donation to the Institute or any foundation created to benefit the Institute, then the Institute shall take appropriate action. Appropriate action may entail:

(A) Withdrawal of the Grant Application from further consideration; or

(B) Return of the donation, if the return of the donation is possible without impairing Institute operations.

(8) If the donation is returned to the Applicant, then the Grant Application is eligible to be considered for a Grant Award.

(i) Grant Applicants shall identify by name all sources of funding contributing to the project proposed for a Grant Award. A Grant Applicant for a Product Development Research Grant Award must provide a capitalization table that includes those individuals or entities that have an investment, stock or rights in the company. The Institute shall make the information provided by the Grant Applicant available to Scientific Research and Prevention Programs Committee members, Institute employees, independent contractors participating in the Grant Review Process, Program Integration Committee Members and Oversight Committee Members for purposes of identifying potential Conflicts of Interest prior to reviewing or taking action on the Grant Application. The information shall be maintained in the Institute's Grant Review Process records.

(j) A Grant Applicant shall indicate if the Grant Applicant is currently ineligible to receive Federal or State grant funds due to debarment or suspension or if the Grant Applicant has had a grant terminated for cause within five years prior to the submission date of the Grant Application. For purposes of the provision, the term Grant Applicant includes the personnel, including collaborators or contractors, who will be working on the Grant Award. A Grant Applicant is not eligible to receive a Grant Award if the Grant Applicant is debarred, suspended, ineligible or otherwise excluded from participation in a federal or state grant award.

(k) The Institute may require each Grant Applicant for a Cancer Research Grant Award for Product Development to submit an application fee.

(1) The Chief Executive Officer shall adopt a policy regarding the application fee amount.

(2) The Institute shall use the application fee amounts to defray the Institute's costs associated with the Product Development review processes, including due diligence and intellectual property reviews, as specified in the Request for Application.

(3) Unless a request to submit the fee after the deadline has been approved by the Institute, the Institute may administratively withdraw a Grant Application if the application review fee is not received by the Institute within seven business days of the Grant Application submission deadline.

(4) Upon a written request from the Grant Applicant, the Institute may refund the application fee to the Grant Applicant if the Grant Applicant withdraws the Grant Application or the Grant Application is otherwise removed from the Grant Review Process prior to the review of the Grant Application by the Scientific Research and Prevention Programs Committees. The Institute's decision regarding return of the application fee is final.

(l) During the course of administrative review of the Grant Application, the Institute may contact the Grant Applicant to seek clarification on information provided in the Grant Application or to request additional information if such information clarifies the Grant Application. The Institute shall keep a record of requests made under this subsection for review by the Chief Compliance Officer.

§703.13.Audits and Investigations.

(a) Upon request and with reasonable notice, an entity receiving Grant Award funds directly under the Grant Contract or indirectly through a subcontract under the Grant Contract shall allow, or shall cause the entity that is maintaining such items to allow the Institute, or auditors or investigators working on behalf of the Institute, including the State Auditor and/or the Comptroller of Public Accounts for the State of Texas, to review, inspect, audit, copy or abstract its records pertaining to the specific Grant Contract during the term of the Grant Contract and for the three year period following the date the last disbursement of funds is made by the Institute or all reports required pursuant to the Grant Contract are submitted and approved, whichever date is later.

(1) A Grant Recipient shall maintain its records pertaining to the specific Grant Contract for a period of three years following the date the last disbursement of funds is made by the Institute or all reports required pursuant to the Grant Contract are submitted and approved, whichever date is later.

(2) The Grant Recipient may maintain its records in either electronic or paper format.

(b) Notwithstanding the foregoing, the Grant Recipient shall submit a single audit determination form no later than 60 days following the close of the Grant Recipient's fiscal year. The Grant Recipient shall report whether the Grant Recipient has expended $750,000 or more in state awards during the Grant Recipient's fiscal year. If the Grant Recipient has expended $750,000 or more in state awards in its fiscal year, the Grant Recipient shall obtain either an annual single independent audit, a program specific independent audit, or an agreed upon procedures engagement as defined by the American Institute of Certified Public Accountants and pursuant to guidance provided in subsection (e) of this section.

(1) The audited time period is the Grant Recipient's fiscal year.

(2) The audit must be submitted to the Institute within thirty (30) days of receipt by the Grant Recipient but no later than nine (9) months following the close of the Grant Recipient's fiscal year and shall include a corrective action plan that addresses any weaknesses, deficiencies, wrongdoings, or other concerns raised by the audit report and a summary of the action taken by the Grant Recipient to address the concerns, if any, raised by the audit report.

(A) The Grant Recipient may seek additional time to submit the required audit and corrective action plan by providing a written explanation for its failure to timely comply and providing an expected time for the submission.

(B) The Grant Recipient's request for additional time must be submitted on or before the due date of the required audit and corrective action plan. For purposes of this rule, the "due date of the required audit" is no later than nine (9) months following the close of the Grant Recipient's fiscal year.

(C) Approval of the Grant Recipient's request for additional time is at the discretion of the Institute. Such approval must be granted by the Chief Executive Officer.

(c) No reimbursements or advances of Grant Award funds shall be made to the Grant Recipient if the Grant Recipient is delinquent in filing the required audit and corrective action plan. A Grant Recipient that has received approval from the Institute for additional time to file the required audit and corrective action plan may receive reimbursements or advances of Grant Award funds during the pendency of the delinquency unless the Institute's approval declines to permit reimbursements or advances of Grant Award funds until the delinquency is addressed.

(d) A Grant Recipient that is delinquent in submitting to the Institute the audit and corrective action plan required by this section is not eligible to be awarded a new Grant Award or a continuation Grant Award until the required audit and corrective action plan are submitted. A Grant Recipient that has received approval from the Institute for additional time to file the required audit and corrective action plan may remain eligible to be awarded a new Grant Award or a continuation Grant Award unless the Institute's approval declines to continue eligibility during the pendency of the delinquency.

(e) For purposes of this rule, an agreed upon procedures engagement is one in which an independent certified public accountant is hired by the Grant Recipient to issue a report of findings based on specific procedures to be performed on a subject matter.

(1) The option to perform an agreed upon procedures engagement is intended for a non-profit or for-profit Grant Recipient that is not subject to Generally Accepted Government Audit Standards (also known as the Yellow Book) published by the U.S. Government Accountability Office.

(2) The agreed upon procedures engagement will be conducted in accordance with attestation standards established by the American Institute of Certified Public Accountants.

(3) The certified public accountant is to perform procedures prescribed by the Institute and to report his or her findings attesting to whether the Grant Recipient records is in agreement with stated criteria.

(4) The agreed upon procedures apply to all current year expenditures for Grant Awards received by the Grant Recipient. Nothing herein prohibits the use of a statistical sample consistent with the American Institute of Certified Public Accountants' guidance regarding government auditing standards and 2 CFR Part 200, Subpart F, "Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards."

(5) At a minimum, the agreed upon procedures report should address:

(A) Processes and controls;

(B) The Grant Contract;

(C) Indirect Costs;

(D) Matching Funds, if appropriate;

(E) Grant Award expenditures (payroll and non-payroll related transactions);

(F) Equipment;

(G) Revenue Sharing and Program Income;

(H) Reporting; and

(I) Grant Award closeout.

(6) The certified public accountant should consider the specific Grant Mechanism and update or modify the procedures accordingly to meet the requirements of each Grant Award and the Grant Contract reviewed.

(f) If a deadline set by this rule falls on a Saturday, Sunday, or federal holiday as designated by the U.S. Office of Personnel Management, the required filing may be submitted on the next business day. The Institute will not consider a required filing delinquent if the Grant Recipient complies with this subsection.

§703.21.Monitoring Grant Award Performance and Expenditures.

(a) The Institute, under the direction of the Chief Compliance Officer, shall monitor Grant Awards to ensure that Grant Recipients comply with applicable financial, administrative, and programmatic terms and conditions and exercise proper stewardship over Grant Award funds. Such terms and conditions include requirements set forth in statute, administrative rules, and the Grant Contract.

(b) Methods used by the Institute to monitor a Grant Recipient's performance and expenditures may include:

(1) Financial Status Reports Review--The Institute shall review Grant Award expenditures reported by Grant Recipients on the quarterly Financial Status Reports and supporting documents to determine whether expenses charged to the Grant Award are:

(A) Allowable, allocable, reasonable, necessary, and consistently applied regardless of the source of funds; and

(B) Adequately supported with documentation such as cost reports, receipts, third party invoices for expenses, or payroll information.

(2) Timely submission of Grant Award Reports--The Institute shall monitor the submission of all required reports and implement a process to ensure that Grant Award funds are not disbursed to a Grant Recipient with one or more delinquent reports.

(3) Grant Progress Reports--The Institute shall review Grant Progress Reports to determine whether sufficient progress is made consistent with the scope of work and timeline set forth in the Grant Contract.

(A) The Grant Progress Reports shall be submitted at least annually, but may be required more frequently pursuant to Grant Contract terms or upon request and reasonable notice of the Institute.

(B) Unless specifically stated otherwise herein, the annual Grant Progress Report shall be submitted within sixty (60) days after the anniversary of the effective date of the Grant Contract. The annual Grant Progress Report shall include at least the following information:

(i) An affirmative verification by the Grant Recipient of compliance with the terms and conditions of the Grant Contract;

(ii) A description of the Grant Recipient's progress made toward completing the scope of work specified by the Grant Contract, including information, data, and program metrics regarding the achievement of project goals and timelines;

(iii) The number of new jobs created and the number of jobs maintained for the preceding twelve month period as a result of Grant Award funds awarded to the Grant Recipient for the project;

(iv) An inventory of the equipment purchased for the project in the preceding twelve month period using Grant Award funds;

(v) A verification of the Grant Recipient's efforts to purchase from suppliers in this state more than 50 percent goods and services purchased for the project with grant funds;

(vi) A Historically Underutilized Businesses report;

(vii) Scholarly articles, presentations, and educational materials produced for the public addressing the project funded by the Institute;

(viii) The number of patents applied for or issued addressing discoveries resulting from the research project funded by the Institute;

(ix) A statement of the identities of the funding sources, including amounts and dates for all funding sources supporting the project;

(x) A verification of the amounts of Matching Funds dedicated to the research that is the subject of the Grant Award for the period covered by the annual report, which shall be submitted pursuant to the timeline in §703.11 of this title (relating to Requirement to Demonstrate Available Funds for Cancer Research Grants). In order to receive disbursement of grant funds, the most recently due verification of the amount of Matching Funds must be approved by CPRIT;

(xi) All financial information necessary to support the calculation of the Institute's share of revenues, if any, received by the Grant Recipient resulting from the project; and

(xii) A single audit determination form, which shall be submitted pursuant to the timeline in §703.13 of this title (relating to Audits and Investigations).

(C) Notwithstanding subparagraph (B) of this paragraph, in the event that the Grant Recipient and Institute execute the Grant Contract after the effective date of the Grant Contract, the Chief Program Officer may approve additional time for the Grant Recipient to prepare and submit the outstanding reports. The approval shall be in writing and maintained in the Institute's electronic Grants Management System. The Chief Program Officer's approval may cover more than one report and more than one fiscal quarter.

(D) In addition to annual Grant Progress Reports, a final Grant Progress Report shall be filed no more than ninety (90) days after the termination date of the Grant Contract. The final Grant

Progress Report shall include a comprehensive description of the Grant Recipient's progress made toward completing the scope of work specified by the Grant Contract, as well as other information specified by the Institute.

(E) The Grant Progress Report will be evaluated pursuant to criteria established by the Institute. The evaluation shall be conducted under the direction of the Chief Prevention Officer, the Chief Product Development Officer, or the Chief Scientific Officer, as may be appropriate. Required financial reports associated with the Grant Progress Report will be reviewed by the Institute's financial staff. In order to receive disbursement of grant funds, the final progress report must be approved by CPRIT.

(F) If the Grant Progress Report evaluation indicates that the Grant Recipient has not demonstrated progress in accordance with the Grant Contract, then the Chief Program Officer shall notify the Chief Executive Officer and the General Counsel for further action.

(i) The Chief Program Officer shall submit written recommendations to the Chief Executive Officer and General Counsel for actions to be taken, if any, to address the issue.

(ii) The recommended action may include termination of the Grant Award pursuant to the process described in §703.14 of this chapter (relating to Termination, Extension, and Close Out of Grant Contracts, and De-Obligation of Grant Award Funds).

(G) If the Grant Recipient fails to submit required financial reports associated with the Grant Progress Report, then the Institute financial staff shall notify the Chief Executive Officer and the General Counsel for further action.

(H) In order to receive disbursement of grant funds, the most recently due progress report must be approved by CPRIT.

(I) If a Grant Recipient fails to submit the Grant Progress Report within 60 days of the anniversary of the effective date of the Grant Contract, then the Institute shall not disburse any Grant Award funds as reimbursement or advancement of Grant Award funds until such time that the delinquent Grant Progress Report is approved.

(J) In addition to annual Grant Progress Reports, Product Development Grant Recipients shall submit a Grant Progress Report at the completion of specific tranches of funding specified in the Award Contract. For the purpose of this subsection, a Grant Progress Report submitted at the completion of a tranche of funding shall be known as "Tranche Grant Progress Report."

(i) The Institute may specify other required reports, if any, that are required to be submitted at the time of the Tranche Grant Progress Report.

(ii) Grant Funds for the next tranche of funding specified in the Grant Contract shall not be disbursed until the Tranche Grant Progress Report has been reviewed and approved pursuant to the process described in this section.

(K) A Grant Award in the prevention program with a Grant Contract effective date within the last quarter of a state fiscal year (June 1-August 31) will have an initial reporting period beginning September 1 of the following state fiscal year.

(4) Desk Reviews--The Institute may conduct a desk review for a Grant Award to review and compare individual source documentation and materials to summary data provided during the Financial Status Report review for compliance with financial requirements set forth in the statute, administrative rules, and the Grant Contract.

(5) Site Visits and Inspection Reviews--The Institute may conduct a scheduled site visit to a Grant Recipient's place of business to review Grant Contract compliance and Grant Award performance issues. Such site visits may be comprehensive or limited in scope.

(6) Audit Reports--The Institute shall review audit reports submitted pursuant to §703.13 of this chapter (relating to Audits and Investigations).

(A) If the audit report findings indicate action to be taken related to the Grant Award funds expended by the Grant Recipient or for the Grant Recipient's fiscal processes that may impact Grant Award expenditures, the Institute and the Grant Recipient shall develop a written plan and timeline to address identified deficiencies, including any necessary Grant Contract amendments.

(B) The written plan shall be retained by the Institute as part of the Grant Contract record.

(c) All required Grant Recipient reports and submissions described in this section shall be made via an electronic grant portal designated by the Institute, unless specifically directed to the contrary in writing by the Institute.

(d) The Institute shall document the actions taken to monitor Grant Award performance and expenditures, including the review, approvals, and necessary remedial steps, if any.

(1) To the extent that the methods described in subsection (b) of this section are applied to a sample of the Grant Recipients or Grant Awards, then the Institute shall document the Grant Contracts reviewed and the selection criteria for the sample reviewed.

(2) Records will be maintained in the electronic Grant Management System as described in §703.4 of this chapter (relating to Grants Management System).

(e) The Chief Compliance Officer shall be engaged in the Institute's Grant Award monitoring activities and shall notify the General Counsel and Oversight Committee if a Grant Recipient fails to meaningfully comply with the Grant Contract reporting requirements and deadlines, including Matching Funds requirements.

(f) The Chief Executive Officer shall report to the Oversight Committee at least annually on the progress and continued merit of each Grant Program funded by the Institute. The written report shall also be included in the Annual Public Report. The report should be presented to the Oversight Committee at the first meeting following the publication of the Annual Public Report.

(g) The Institute may rely upon third parties to conduct Grant Award monitoring services independently or in conjunction with Institute staff.

(h) If a deadline set by this rule falls on a Saturday, Sunday, or federal holiday as designated by the U.S. Office of Personnel Management, the required filing may be submitted on the next business day. The Institute will not consider a required filing delinquent if the Grant Recipient complies with this subsection.

§703.22.Required Training for Grant Recipients.

(a) The Institute, under the direction of the Chief Compliance Officer, shall create a compliance training program for Grant Recipients addressing applicable financial, administrative, and programmatic requirements related to proper stewardship over Grant Award funds, including grant reporting.

(b) Initial Grant Recipient training program - A Grant Recipient that is approved for a Grant Award for the first time on or after September 1, 2015, shall complete an initial compliance training program. For purposes of this subsection, a Grant Recipient that has received at least one Grant Award prior to September 1, 2015, is not required to complete the initial compliance training program.

(1) The Chief Compliance Officer shall design the initial compliance training program.

(2) The Grant Recipient must complete the initial compliance training program prior to receiving disbursement of Grant Award funds, unless the Chief Compliance Officer finds good cause to disburse grant funds in advance of completing the initial compliance training program.

(3) Nothing herein prohibits the Chief Compliance Officer from requiring a Grant Recipient to complete the initial compliance training program.

(c) Annual Grant Recipient training program - All Grant Recipients shall complete an annual compliance training program by November 1, 2016, and then by December 31 of each year thereafter that the Grant Recipient has at least one active Grant Award.

(1) The Chief Compliance Officer shall design the annual compliance training program.

(2) The Institute shall withhold disbursement of Grant Award funds if the Grant Recipient fails to complete the annual compliance training program by November 1, unless the Chief Compliance Officer finds good cause to disburse grant funds in advance of completing the annual compliance training program.

(d) Grant Recipient personnel required to attend training - The Grant Recipient's Authorized Signing Official and at least one other individual employed by the Grant Recipient must attend the trainings required by this rule.

(1) Upon a finding of good cause, the Chief Compliance Officer may allow the Grant Recipient to substitute another employee to attend a required training in place of the Authorized Signing Official.

(2) In the event that the Authorized Signing Official designated by the Grant Recipient changes on or after November 1, 2016, and the new Authorized Signing Official has not completed the annual compliance training program, the new Authorized Signing Official shall complete the annual compliance training program within 60 days of change. Failure to do so may result in the withholding of Grant Award funds until the training is completed.

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	KRISTEN PAULING DOYLE, GENERAL COUNSEL CAMERON L. ECKEL, STAFF ATTORNEY
SUBJECT:	CHAPTER 703 PROPOSED RULE CHANGES
DATE:	FEBRUARY 8, 2019

Summary and Recommendation

The Board Governance Subcommittee recommends that the Oversight Committee approve the proposed administrative rule changes for publication in the *Texas Register* for public comment. The proposed changes affect Texas Administrative Code Chapter 703.

Discussion

CPRIT's administrative rules set policy guiding CPRIT's grant review and grant contracting processes as well as administering other requirements of Texas Health and Safety Code Chapter 102. State law requires agencies to use a rulemaking process, which includes an opportunity for the public to comment on proposed rules and rule changes before the agency adopts the final policy.

The Board Governance subcommittee met on February 7th to discuss the proposed rule changes Chapter 703 with legal staff.

- The proposed amendment to §703.6(e)(4)(B) clarifies that the Product Development Review Council (PDRC) may conduct business operations and management due diligence for product development applications. Grant applications for product development awards go through the additional step of business and intellectual property due diligence. CPRIT contracts with an outside vendor to perform the business diligence. The rule change permits CPRIT to use one or more PDRC members to perform due diligence due to logistical needs or to address special areas of expertise.

- The proposed amendment to § 703.13(f) clarifies the areas that grantees should cover if they are submitting a program specific audit to CPRIT. Grantees who expend $750,000 or more in state funds are required to submit an independent audit,

PO Box 12097 | Austin, Texas 78711 | PH: 512-463-3190 | F: 512-475-2563 | cprit.texas.gov

a program specific audit, or an agreed upon procedures engagement. The change to § 703.13 elaborates on what the information included in the program specific audit. CPRIT's *Policies and Procedure Guide* will also be updated to provide explanation of program specific audit requirements.

- The proposed amendment to § 703.26(e)(4)(B) clarifies the unallowable grantee expenses includes fundraising and tips or gratuities. This change ensures that CPRIT's administrative rules are consistent with current processes for disallowing expenses by other applicable resources.

The subcommittee voted to recommend approval and publication of the proposed rule changes to the Oversight Committee.

Next Steps

CPRIT will publish the proposed rule changes in the *Texas Register*. The publication date begins the 30-day period soliciting public comment. CPRIT will post the proposed rule on CPRIT's website and announce the opportunity for public comment via the CPRIT electronic list serve. CPRIT legal staff will summarize all public comments for the Oversight Committee's consideration when approving the final rule changes in May.

The Cancer Prevention and Research Institute of Texas (CPRIT or the Institute) proposes amendments to 25 Tex. Admin. Code §§703.6, 703.13, and 703.26. The proposed amendments clarify product development grant application review, program specific audit methodology for grantees, and unallowable costs.

Background and Justification

The proposed amendment to §703.6(e)(4)(B) clarifies that the Product Development Review Council (PDRC) may perform business operations and management due diligence for product development application, which go through both business and intellectual property due diligence. The proposed change to §703.13(f) clarifies what areas need to be included in a program specific audit provided by a grantee. Grant recipients who expend $750,000 or more in state funds are required to submit a single independent audit, program specific audit, or agreed upon procedures engagement. There are certain expenses that grant recipients may not expend grant funds on and the proposed amendment to §703.26(e) clarifies the unallowable expenses include fundraising and tips or gratuities.

Fiscal Note

Kristen Pauling Doyle, Deputy Executive Officer and General Counsel for the Cancer Prevention and Research Institute of Texas, has determined that for the first five-year period the rule changes are in effect, there will be no foreseeable implications relating to costs or revenues for state or local government due to enforcing or administering the rules.

Public Benefit and Costs

Ms. Doyle has determined that for each year of the first five years the rule changes are in effect the public benefit anticipated due to enforcing the rule will be clarifying processes regarding grant review, specifying information to be included in single audit reviews, and specifying additional categories of unallowable expenses.

Small Business, Micro-Business, and Rural Communities Impact Analysis

Ms. Doyle has determined that the rule changes will not affect small businesses, micro businesses, or rural communities.

Government Growth Impact Statement

The Institute, in accordance with 34 Texas Administrative Code §11.1, has determined that during the first five years that the proposed rule changes will be in effect:

(1) the proposed rule changes will not create or eliminate a government program;

(2) implementation of the proposed rule changes will not affect the number of employee positions;

(3) implementation of the proposed rule changes will not require an increase or decrease in future legislative appropriations;

(4) the proposed rule changes will not affect fees paid to the agency;

(5) the proposed rule changes will not create new rules;

(6) the proposed rule changes will not expand existing rules;

(7) the proposed rule changes will not change the number of individuals subject to the rules; and

(8) The rule changes are unlikely to have a significant impact on the state's economy. Although these changes are likely to have neutral impact on the state's economy, the Institute lacks enough data to predict the impact with certainty.

Submit written comments on the proposed rule changes to Ms. Kristen Pauling Doyle, General Counsel, Cancer Prevention and Research Institute of Texas, P. O. Box 12097, Austin, Texas 78711, no later than April 29, 2019. The Institute asks parties filing comments to indicate whether they support the rule revisions proposed by the Institute and, if a change is requested, to provide specific text proposed to be included in the rule. Comments may be submitted electronically to kdoyle@cprit.texas.gov. Comments may be submitted by facsimile transmission to 512/475-2563.

Statutory Authority

The Institute proposes the rule changes under the authority of the Texas Health and Safety Code Annotated, §102.108, which provides the Institute with broad rule-making authority to administer the chapter. Ms. Doyle has reviewed the proposed amendments and certifies the proposal to be within the Institute's authority to adopt.

There is no other statute, article, or code affected by these rules.

<rule>

§703.6. Grant Review Process.

(a) For all Grant Applications that are not administratively withdrawn by the Institute for noncompliance or otherwise withdrawn by the Grant Applicant, the Institute shall use a two-stage Peer Review process.

(1) The Peer Review process, as described herein, is used to identify and recommend meritorious Cancer Research projects, including those projects with Cancer Research Product Development prospects, and evidence-based Cancer Prevention and Control projects for Grant Award consideration by the Program Integration Committee and the Oversight Committee.

(2) Peer Review will be conducted pursuant to the requirements set forth in Chapter 702 of this title (relating to Institute Standards on Ethics and Conflicts, Including the Acceptance of Gifts and Donations to the Institute) and Chapter 102, Texas Health and Safety Code.

(b) The two stages of the Peer Review Process used by the Institute are:

(1) Evaluation of Grant Applications by Peer Review Panels; and

(2) Prioritization of Grant Applications by the Prevention Review Council, the Product Development Review Council, or the Scientific Review Council, as may be appropriate for the Grant Program.

(c) Except as described in subsection (e) of this section, the Peer Review Panel evaluation process encompasses the following actions, which will be consistently applied:

(1) The Institute distributes all Grant Applications submitted for a particular Grant Mechanism to one or more Peer Review Panels.

(2) The Peer Review Panel chairperson assigns each Grant Application to no less than two panel members that serve as the Primary Reviewers for the Grant Application. Assignments are made based upon the expertise and background of the Primary Reviewer in relation to the Grant Application.

(3) The Primary Reviewer is responsible for individually evaluating all components of the Grant Application, critiquing the merits according to explicit criteria published in the Request for Applications, and providing an individual Overall Evaluation Score that conveys the Primary Reviewer's general impression of the Grant Application's merit. The Primary Reviewers' individual Overall Evaluation Scores are averaged together to produce a single initial Overall Evaluation Score for the Grant Application.

(4) The Peer Review Panel meets to discuss the Grant Applications assigned to the Peer Review Panel. If there is insufficient time to discuss all Grant Applications, the Peer Review Panel chairperson determines the Grant Applications to be discussed by the panel. The chairperson's decision is based largely on the Grant Application's initial Overall Evaluation Score; however a Peer Review Panel member may request that a Grant Application be discussed by the Peer Review Panel.

(A) If a Grant Application is not discussed by the Peer Review Panel, then the initial Overall Evaluation Score serves as the final Overall Evaluation Score for the Grant Application. The Grant Application is not considered further during the Grant Review Cycle.

(B) If a Grant Application is discussed by the Peer Review Panel, each Peer Review Panel member submits a score for the Grant Application based on the panel member's general impression of the Grant Application's merit and accounting for the explicit criteria published in the Request for Applications. The submitted scores are averaged together to produce the final Overall Evaluation Score for the Grant Application.

(i) The panel chairperson participates in the discussion but does not score Grant Applications.

(ii) A Primary Reviewer has the option to revise his or her score for the Grant Application after panel discussion or to keep the same score submitted during the initial review.

(C) If the Peer Review Panel recommends changes to the Grant Award funds amount requested by the Grant Applicant or to the goals and objectives or timeline for the proposed project, then the recommended changes and explanation shall be recorded at the time the final Overall Evaluation Score is set.

(5) At the conclusion of the Peer Review Panel evaluation, the Peer Review Panel chairperson submits to the appropriate Review Council a list of Grant Applications discussed by the panel ranked in order by the final Overall Evaluation Score. Any changes to the Grant Award funding amount or to the project goals and objectives or timeline recommended by the Peer Review Panel shall be provided to the Review Council at that time.

(d) The Review Council's prioritization process for Grant Award recommendations encompasses the following actions, which will be consistently applied:

(1) The Review Council prioritizes the Grant Application recommendations across all the Peer Review Panels by assigning a Numerical Ranking Score to each Grant Application that was discussed by a Peer Review Panel. The Numerical Ranking Score is substantially based on the final Overall Evaluation Score submitted by the Peer Review Panel, but also takes into consideration how well the Grant Application achieves program priorities set by the Oversight Committee, the overall Program portfolio balance, and any other criteria described in the Request for Applications.

(2) The Review Council's recommendations are submitted simultaneously to the presiding officers of the Program Integration Committee and Oversight Committee. The recommendations, listed in order by Numerical Ranking Score shall include:

(A) An explanation describing how the Grant Application meets the Review Council's standards for Grant Award funding;

(B) The final Overall Evaluation Score assigned to the Grant Application by the Peer Review Panel, including an explanation for ranking one or more Grant Applications ahead of another Grant Application with a more favorable final Overall Evaluation Score; and

(C) The specified amount of the Grant Award funding for each Grant Application, including an explanation for recommended changes to the Grant Award funding amount or to the goals and objectives or timeline.

(3) A Grant Award recommendation is not final until the Review Council formally submits the recommendation to the presiding officers of the Program Integration Committee and the Oversight Committee. The Program Integration Committee, and, if appropriate, the Oversight Committee must make a final decision on the Grant Award recommendation in the same state fiscal year that the Review Council submits its final recommendation.

(e) Circumstances relevant to a particular Grant Mechanism or to a Grant Review Cycle may justify changes to the dual-stage Peer Review process described in subsections (c) and (d) of this section. Peer Review process changes the Institute may implement are described in this subsection. The list is not intended to be exhaustive. Any material changes to the Peer Review process, including those listed in this subsection, shall be described in the Request for Applications or communicated to all Grant Applicants.

(1) The Institute may use a preliminary evaluation process if the volume of Grant Applications submitted pursuant to a specific Request for Applications is such that timely review may be

impeded. The preliminary evaluation will be conducted after Grant Applications are assigned to Peer Review Panels but prior to the initial review described in subsection (c) of this section. The preliminary evaluation encompasses the following actions:

(A) The criteria and the specific Grant Application components used for the preliminary evaluation shall be stated in the Request for Applications;

(B) No less than two Peer Review Panel members are assigned to conduct the preliminary evaluation for a Grant Application and provide a preliminary score that conveys the general impression of the Grant Application's merit pursuant to the specified criteria; and

(C) The Peer Review Panel chairperson is responsible for determining the Grant Applications that move forward to initial review as described in subsection (c) of this section. The decision will be based upon preliminary evaluation scores. A Grant Application that does not move forward to initial review will not be considered further and the average of the preliminary evaluation scores received becomes the final Overall Evaluation Score for the Grant Application.

(2) The Institute shall assign all Grant Applications submitted for recruitment of researchers and clinicians to the Scientific Review Council.

(A) The Scientific Review Council members review all components of the Grant Application, evaluate the merits according to explicit criteria published in the Request for Applications, and, after discussion by the Review Council members, provide an individual Overall Evaluation Score that conveys the Review Council member's recommendation related to the proposed recruitment.

(B) The individual Overall Evaluation Scores are averaged together for a final Overall Evaluation Score for the Application.

(C) If more than one recruitment Grant Application is reviewed by the Scientific Review Council during the Grant Review Cycle, then the Scientific Review Council shall assign a Numerical Ranking Score to each Grant Application to convey its prioritization ranking.

(D) If the Scientific Review Council recommends a change to the Grant Award funds requested by the Grant Application, then the recommended change and explanation shall be recorded at the time the final Overall Evaluation Score is set.

(E) The Scientific Review Council's recommendations shall be provided to the presiding officer of the Program Integration Committee and to the Oversight Committee pursuant to the process described in subsection (d) of this section.

(3) The Institute may assign continuation Grant Applications to the appropriate Review Council.

(A) The Review Council members review all components of the Grant Application, evaluate the merits according to explicit criteria published in the Request for Applications, and, after discussion by the Review Council members, provide an individual Overall Evaluation Score that

conveys the Review Council member's recommendation related to the progress and continued funding.

(B) The individual Overall Evaluation Scores are averaged together for a final Overall Evaluation Score for the Application.

(C) If more than one continuation Grant Application is reviewed by the Review Council during the Grant Review Cycle, then the Review Council shall assign a Numerical Ranking Score to each continuation Grant Application to convey its prioritization ranking.

(D) If the Review Council recommends a change to the Grant Award funds or to the scope of work or timeline requested by the continuation Grant Application, then the recommended change and explanation shall be recorded at the time the final Overall Evaluation Score is set.

(E) The Review Council's recommendations shall be provided to the presiding officer of the Program Integration Committee and to the Oversight Committee pursuant to the process described in subsection (d) of this section.

(4) The Institute's Peer Review process described in subsections (c) and (d) of this section may include the following additional process steps for Product Development of Cancer Research Grant Applications:

(A) A Grant Applicant may be invited to deliver an in-person presentation to the Peer Review Panel. The Product Development Review Council chairperson is responsible for deciding which Grant Applicants will make in-person presentations. The decision is based upon the initial Overall Evaluation Scores of the primary reviewers following a discussion with Peer Review Panel members, as well as explicit criteria published in the Request for Applications.

(i) Peer Review Panel members may submit questions to be addressed by the Grant Applicant at the in-person presentation.

(ii) A Grant Application that is not presented in-person will not be considered further. The average of the primary reviewers' initial Overall Evaluation Scores will be the final Overall Evaluation Score for the Grant Application.

(iii) Following the in-person presentation, each Peer Review Panel member submits a score for the Grant Application based on the panel member's general impression of the Grant Application's merit and accounting for the explicit criteria published in the Request for Applications. The submitted scores are averaged together to produce the final Overall Evaluation Score for the Grant Application.

(B) A Grant Application may undergo business operations and management due diligence review and an intellectual property review ~~[conducted by third parties]~~. The Peer Review Panel submits a list of applications recommended for due diligence review to the Product Development Review Council. The Product Development Review Council decides which Grant Applications submitted by the Peer Review Panel will undergo business operations and management due diligence and intellectual property review. The decision is based upon the Grant Application's final Overall Evaluation Score, but also takes into consideration how well the Grant Application

achieves program priorities set by the Oversight Committee, the overall Program portfolio balance, and any other criteria described in the Request for Applications. A Grant Application that is not recommended for due diligence and intellectual property review will not be considered further.

(i) Business operations and management due diligence may be conducted by an outside vendor, contracted by the Institute or by members of the Product Development Review Council.

(ii) It will be at the Institute's discretion as to who to use to perform business operations and management due diligence; factors may include volume of work and expertise required.

(C) After receipt of the business operations and management due diligence and intellectual property reviews for a Grant Application, the Product Development Review Council and the Primary Reviewers meet to determine whether to recommend the Grant Application for a Grant Award based upon the information set forth in the due diligence and intellectual property reviews. The Product Development Review Council may recommend changes to the Grant Award budget and goals and objectives or timeline

(D) The Product Development Review Council assigns a Numerical Ranking Score to each Grant Application recommended for a Grant Award.

(f) Institute Employees and Oversight Committee members may attend Peer Review Panel and Review Council meetings. If an Institute Employee or an Oversight Committee member attends a Peer Review Panel meeting or a Review Council meeting, the attendance shall be recorded and the Institute Employee or Oversight Committee member shall certify in writing compliance with the Institute's Conflict of Interest rules. The Institute Employee's and Oversight Committee member's attendance at the Peer Review Panel meeting or Review Council meeting is subject to the following restrictions:

(1) Unless waived pursuant to the process described in Chapter 702, §702.17 of this title (relating to Exceptional Circumstances Requiring Participation), Institute Employees and Oversight Committee members shall not be present for any discussion, vote, or other action taken related to a Grant Applicant if the Institute Employee or Oversight Committee member has a Conflict of Interest with that Grant Applicant; and

(2) The Institute Employee or Oversight Committee member shall not participate in a discussion of the merits, vote, or other action taken related to a Grant Application, except to answer technical or administrative questions unrelated to the merits of the Grant Application and to provide input on the Institute's Grant Review Process.

(g) The Institute's Chief Compliance Officer shall observe meetings of the Peer Review Panel and Review Council where Grant Applications are discussed.

(1) The Chief Compliance Officer shall document that the Institute's Grant Review Process is consistently followed, including observance of the Institute's established Conflict of Interest

rules and that participation by Institute employees, if any, is limited to providing input on the Institute's Grant Review Process and responding to committee questions unrelated to the merits of the Grant Application. Institute Program staff shall not participate in a discussion of the merits, vote, or any other action taken related to a Grant Application.

(2) The Chief Compliance Officer shall report to the Oversight Committee prior to a vote on the award recommendations specifying issues, if any, that are inconsistent with the Institute's established Grant Review Process.

(3) Nothing herein shall prevent the Institute from contracting with an independent third party to serve as a neutral observer of meetings of the Peer Review Panel and/or the Review Council where Grant Applications are discussed and to assume the reporting responsibilities of the Chief Compliance Officer described in this subsection. In the event that the independent third party observes the meeting of the Peer Review Panel and/or the Review Council, then the independent third party reviewer shall issue a report to the Chief Compliance Officer specifying issues, if any, that are inconsistent with the Institute's established Grant Review Process.

(h) Excepting a finding of an undisclosed Conflict of Interest as set forth in §703.9 of this chapter (relating to Limitation on Review of Grant Process), the Review Council's decision to not include a Grant Application on the prioritized list of Grant Applications submitted to the Program Integration Committee and the Oversight Committee is final. A Grant Application not included on the prioritized list created by the Review Council shall not be considered further during the Grant Review Cycle.

(i) At the time that the Peer Review Panel or the Review Council concludes its tasks for the Grant Review Cycle, each member shall certify in writing that the member complied with the Institute's Conflict of Interest rules. An Institute Employee or an Oversight Committee member attending one or more Peer Review Panel meetings during the Grant Review Cycle shall certify compliance with the Institute's Conflict of Interest rules.

(j) The Institute shall retain a review record for a Grant Application submitted to the Institute, even if the Grant Application did not receive a Grant Award. Such records will be retained by the Institute's electronic Grant Management System. The records retained by the Institute must include the following information:

(1) The final Overall Evaluation Score and Numerical Ranking Score, if applicable, assigned to the Grant Application;

(2) The specified amount of the Grant Award funding for the Grant Application, including an explanation for recommended changes to the Grant Award funding amount or to the goals and objectives or timeline;

(3) The Scientific Research and Prevention Programs Committee that reviewed the Grant Application;

(4) Conflicts of Interest, if any, with the Grant Application identified by a member of the Scientific Research and Prevention Programs Committee, the Review Council, the Program Integration Committee, or the Oversight Committee; and

(5) Documentation of steps taken to recuse any member or members from the Grant Review Process because of disclosed Conflicts of Interest.

(k) For purposes of this rule, a Peer Review Panel chairperson or a Review Council chairperson that is unable to carry out his or her assigned duties due to a Conflict of Interest with regard to one or more Grant Applications or for any other reason may designate a co-chairperson from among the appointed Scientific Research and Prevention Programs committee members to fulfill the chairperson role. Such designation shall be recorded in writing and include the specific time and extent of the designation

§703.13. Audits and Investigations.

(a) Upon request and with reasonable notice, an entity receiving Grant Award funds directly under the Grant Contract or indirectly through a subcontract under the Grant Contract shall allow, or shall cause the entity that is maintaining such items to allow the Institute, or auditors or investigators working on behalf of the Institute, including the State Auditor and/or the Comptroller of Public Accounts for the State of Texas, to review, inspect, audit, copy or abstract its records pertaining to the specific Grant Contract during the term of the Grant Contract and for the three year period following the date the last disbursement of funds is made by the Institute or all reports required pursuant to the Grant Contract are submitted and approved, whichever date is later.

(1) A Grant Recipient shall maintain its records pertaining to the specific Grant Contract for a period of three years following the date the last disbursement of funds is made by the Institute or all reports required pursuant to the Grant Contract are submitted and approved, whichever date is later.

(2) The Grant Recipient may maintain its records in either electronic or paper format.

(b) Notwithstanding the foregoing, the Grant Recipient shall submit a single audit determination form no later than 60 days following the close of the Grant Recipient's fiscal year. The Grant Recipient shall report whether the Grant Recipient has expended $750,000 or more in state awards during the Grant Recipient's fiscal year. If the Grant Recipient has expended $750,000 or more in state awards in its fiscal year, the Grant Recipient shall obtain either an annual single independent audit, a program specific independent audit, or an agreed upon procedures engagement as defined by the American Institute of Certified Public Accountants and pursuant to guidance provided in subsection (e) of this section.

(1) The audited time period is the Grant Recipient's fiscal year.

(2) The audit must be submitted to the Institute within thirty (30) days of receipt by the Grant Recipient but no later than nine (9) months following the close of the Grant Recipient's fiscal

year and shall include a corrective action plan that addresses any weaknesses, deficiencies, wrongdoings, or other concerns raised by the audit report and a summary of the action taken by the Grant Recipient to address the concerns, if any, raised by the audit report.

(A) The Grant Recipient may seek additional time to submit the required audit and corrective action plan by providing a written explanation for its failure to timely comply and providing an expected time for the submission.

(B) The Grant Recipient's request for additional time must be submitted on or before the due date of the required audit and corrective action plan. For purposes of this rule, the "due date of the required audit" is no later than nine (9) months following the close of the Grant Recipient's fiscal year.

(C) Approval of the Grant Recipient's request for additional time is at the discretion of the Institute. Such approval must be granted by the Chief Executive Officer.

(c) No reimbursements or advances of Grant Award funds shall be made to the Grant Recipient if the Grant Recipient is delinquent in filing the required audit and corrective action plan. A Grant Recipient that has received approval from the Institute for additional time to file the required audit and corrective action plan may receive reimbursements or advances of Grant Award funds during the pendency of the delinquency unless the Institute's approval declines to permit reimbursements or advances of Grant Award funds until the delinquency is addressed.

(d) A Grant Recipient that is delinquent in submitting to the Institute the audit and corrective action plan required by this section is not eligible to be awarded a new Grant Award or a continuation Grant Award until the required audit and corrective action plan are submitted. A Grant Recipient that has received approval from the Institute for additional time to file the required audit and corrective action plan may remain eligible to be awarded a new Grant Award or a continuation Grant Award unless the Institute's approval declines to continue eligibility during the pendency of the delinquency.

(e) For purposes of this rule, an agreed upon procedures engagement is one in which an independent certified public accountant is hired by the Grant Recipient to issue a report of findings based on specific procedures to be performed on a subject matter.

(1) The option to perform an agreed upon procedures engagement is intended for a non-profit or for-profit Grant Recipient that is not subject to Generally Accepted Government Audit Standards (also known as the Yellow Book) published by the U.S. Government Accountability Office.

(2) The agreed upon procedures engagement will be conducted in accordance with attestation standards established by the American Institute of Certified Public Accountants.

(3) The certified public accountant is to perform procedures prescribed by the Institute and to report his or her findings attesting to whether the Grant Recipient records is in agreement with stated criteria.

(4) The agreed upon procedures apply to all current year expenditures for Grant Awards received by the Grant Recipient. Nothing herein prohibits the use of a statistical sample consistent with the American Institute of Certified Public Accountants' guidance regarding government auditing standards and 2 CFR Part 200, Subpart F, "Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards."

(5) At a minimum, the agreed upon procedures report should address:

(A) Processes and controls;

(B) The Grant Contract;

(C) Indirect Costs;

(D) Matching Funds, if appropriate;

(E) Grant Award expenditures (payroll and non-payroll related transactions);

(F) Equipment;

(G) Revenue Sharing and Program Income;

(H) Reporting; and

(I) Grant Award closeout.

(6) The certified public accountant should consider the specific Grant Mechanism and update or modify the procedures accordingly to meet the requirements of each Grant Award and the Grant Contract reviewed.

(f) For purposes of this rule, a program specific audit should address:

(1) sample of awards;

(2) reporting;

(3) Indirect costs;

(4) Matching funds, if appropriate;

(5) expenditures;

(6) Expenditure Reporting;

(7) Personnel Level of Effort Reporting;

(8) Grant Closeout;

(9) Performance Measures;

(10) Publications and Acknowledgements;

(11) Title to equipment;

(12) Contract certifications;

(13) Changes in Principal Investigator or Program Director;

(14) Intellectual Property and revenue sharing;

(15) early termination and event of default; and

(16) any other issue identified by the Institute, the Grant Recipient, or the person performing the program specific audit.

(g)[(f)] If a deadline set by this rule falls on a Saturday, Sunday, or federal holiday as designated by the U.S. Office of Personnel Management, the required filing may be submitted on the next business day. The Institute will not consider a required filing delinquent if the Grant Recipient complies with this subsection.

§703.26. Allowable Costs.

(a) A cost is an Allowable Cost and may be charged to the Grant Award if it is reasonable, allocable, and adequately documented.

(1) A cost is reasonable if the cost does not exceed that which would be incurred by a prudent individual or organization under the circumstances prevailing at the time the decision was made to incur the cost; and is necessary for the performance of the Grant Award defined in the Scope of Work in the Grant Contract.

(2) A cost is allocable if the cost:

(A) Benefits the Grant Award either directly or indirectly, subject to Indirect Cost limits stated in the Grant Contract;

(B) Is assigned the Grant Award in accordance with the relative benefit received;

(C) Is allowed or not prohibited by state laws, administrative rules, contractual terms, or applicable regulations;

(D) Is not included as a cost or used to meet Matching Fund requirements for any other Grant Award in either the current or a prior period; and

(E) Conforms to any limitations or exclusions set forth in the applicable cost principles, administrative rules, state laws, and terms of the Grant Contract.

(3) A cost is adequately documented if the cost is supported by the organization's accounting records and documented consistent with §703.24.

(b) Grant Award funds must be used for Allowable Costs as provided by the terms of the Grant Contract, Chapter 102, Texas Health and Safety Code, the Institute's administrative rules, and the

Uniform Grant Management Standards (UGMS) adopted by the Comptroller's Office. If guidance from the Uniform Grant Management Standards on a particular issue conflicts with a specific provision of the Grant Contract, Chapter 102, Texas Health and Safety Code or the Institute's administrative rules, then the Grant Contract, statute, or Institute administrative rule shall prevail.

(c) An otherwise Allowable Cost will not be eligible for reimbursement if the Grant Recipient incurred the expense outside of the Grant Contract term, unless the Grant Recipient has received written approval from Institute's Chief Executive Officer to receive reimbursement for expenses incurred prior to the effective date of the Grant Contract.

(d) An otherwise Allowable Cost will not be eligible for reimbursement if the benefit from the cost of goods or services charged to the Grant Award is not realized within the applicable term of the Grant Award. The Grant Award should not be charged for the cost of goods or services that benefit another Grant Award or benefit a period prior to the Grant Contract effective date or after the termination of the Grant Contract.

(e) Grant Award funds shall not be used to reimburse unallowable expenses, including, but not limited to:

(1) Bad debt, such as losses arising from uncollectible accounts and other claims and related costs.

(2) Contributions to a contingency reserve or any similar provision for unforeseen events.

(3) Contributions and donations made to any individual or organization.

(4) Costs of entertainment, amusements, social activities, and incidental costs relating thereto, including tickets to shows or sports events, meals, alcoholic beverages, lodging, rentals, transportation and gratuities.

(5) Costs relating to food and beverage items, unless the food item is related to the issue studied by the project that is the subject of the Grant Award.

(6) Fines, penalties, or other costs resulting from violations of or failure to comply with federal, state, local or Indian tribal laws and regulations.

(7) An honorary gift or a gratuitous payment.

(8) Interest and other financial costs related to borrowing and the cost of financing.

(9) Legislative expenses such as salaries and other expenses associated with lobbying the state or federal legislature or similar local governmental bodies, whether incurred for purposes of legislation or executive direction.

(10) Liability insurance coverage.

(11) Benefit replacement pay or legislatively-mandated pay increases for eligible general revenue-funded state employees at Grant Recipient state agencies or universities.

(12) Professional association fees or dues for the Grant Recipient or an individual.

(13) Promotional items and costs relating to items such as T-shirts, coffee mugs, buttons, pencils, and candy that advertise or promote the project or Grant Recipient.

(14) Fees for visa services.

(15) Payments to a subcontractor if the subcontractor working on a Grant Award project employs an individual who is a Relative of the Principal Investigator, Program Director, Company Representative, Authorized Signing Official, or any person designated as Key Personnel for the same Grant Award project (collectively referred to as "affected Relative"), and:

(A) the Grant Recipient will be paying the subcontractor with Grant Award funds for any portion of the affected Relative's salary; or

(B) the Relative submits payment requests on behalf of the subcontractor to the Grant Recipient for payment with Grant Award funds.

(C) For exceptional circumstances, the Institute's Chief Executive Office may grant an exception to allow payment of Grant Award funds if the Grant Recipient notifies the Institute prior to finalizing the subcontract. The Chief Executive Officer must notify the Oversight Committee in writing of the decision to allow reimbursement for the otherwise unallowable expense.

(D) Nothing herein is intended to supersede a Grant Recipient's internal policies, to the extent that such policies are stricter.

(16) Fundraising.

(17) Tips or gratuities.

(f) The Institute is responsible for making the final determination regarding whether an expense shall be considered an Allowable Cost.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

To:	**OVERSIGHT COMMITTEE MEMBERS**
From:	**HEIDI MCCONNELL, CHIEF OPERATING OFFICER**
Subject:	**CHIEF OPERATING OFFICER REPORT**
Date:	**FEBRUARY 8, 2019**

CPRIT Financial Overview for FY 2019, Quarter 1

FY 2019, Quarter 1 Operating Budget

CPRIT expended or obligated approximately $1.4 million in Indirect Administration and approximately $10.1 million in Grant Review and Award Operations, or approximately 67% of the overall $17.4 million administrative budget for the fiscal year. The bulk of the obligations is

During the first quarter, the agency received $158,052 in revenue sharing payments. This brings the total revenue sharing payments received to date to approximately $3.6 million.

FY 2019, Quarter 1 Performance Measure Report

CPRIT reported first quarter performance to the Legislative Budget Board on the two output measures with quarterly reporting requirements:

1) Number of Cancer Prevention and Control Services Provided, and
2) Number of Entities Relocating to Texas for Cancer Research Related Projects.

Debt Issuance History

In September 2018, the Texas Public Finance Authority issued $75,975,000 of new money in conjunction with $222.2 million of refunding in a long-term debt issuance on CPRIT's behalf.

PO Box 12097 | Austin, Texas 78711 | PH: 512-463-3190 | F: 512-475-2563 | www.cprit.state.tx.us

Cancer Prevention and Research Institute of Texas
Quarterly Financial Report
As of November 30, 2018

Indirect Administration (B.1.1.)

		2019 Appropriated	2019 Budgeted	% of Total Budget	Actual Expenditures & Grant Encumbrances (FYTD)	Remaining Budget	Percent Expended	Estimated Expenditures (YTD)	Lapse/Overspent
1001	Salaries and Wages	$ 1,617,425	$ 1,617,425		$ 333,547	1,283,878	21%	$ 333,547	$ 1,283,878
1002	Other Personnel Costs	38,785	135,816		5,533	130,283	4%	5,533	130,283
2001	Professional Fees and Services	961,664	1,413,164		797,653	615,512	56%	797,653	615,512
2003	Consumable Supplies	24,000	24,000		7,902	16,098	33%	7,902	16,098
2004	Utilities	58,600	58,600		39,094	19,506	67%	39,094	19,506
2005	Travel	45,000	45,000		12,073	32,927	27%	12,073	32,927
2006	Rent-Building	13,700	18,858		18,858	0	0%	18,858	0
2007	Rent-Machine and Other	32,172	32,172		2,954	29,218	9%	2,954	29,218
2009	Other Operating Expenses	473,815	467,157		222,627	244,530	48%	222,627	244,530
	Subtotal - Indirect Administration (B.1.1.)	**$ 3,265,161**	**$ 3,812,192**	**1.28%**	**$ 1,440,241**	**$ 2,371,951**	**38%**	**$ 1,440,241**	**$ 2,371,951**

Grant Review and Award Operations (A.1.3.)

		2019 Appropriated	2019 Budgeted	% of Total Budget	Actual Expenditures & Grant Encumbrances (FYTD)	Remaining Budget	Percent Expended	Estimated Expenditures (YTD)	Lapse/Overspent
1001	Salaries and Wages	$ 3,078,084	3,078,084		$ 817,450	$ 2,260,634	27%	$ 817,450	$ 2,260,634
1002	Other Personnel Costs	45,500	45,500		28,713	16,787	0%	28,713	16,787
2001	Professional Fees and Services	10,151,277	10,250,442		9,242,622	1,007,821	90%	9,242,622	1,007,821
2003	Consumable Supplies	-	-		-	-	0%	-	-
2004	Utilities	12,000	12,000		2,218	9,782	18%	2,218	9,782
2005	Travel	65,000	65,000		8,104	56,896	12%	8,104	56,896
2009	Other Operating Expenses	102,730	96,680		11,363	85,317	12%	11,363	85,317
	Subtotal - Grant Operations (A.1.3.)	**$ 13,454,591**	**$ 13,547,706**	**4.56%**	**$ 10,110,469**	**$ 3,437,237**	**75%**	**$ 10,110,469**	**$ 3,437,237**

Grants

		2019 Appropriated	2019 Budgeted	% of Total Budget	Actual Expenditures & Grant Encumbrances (FYTD)	Remaining Budget	Percent Expended	Estimated Expenditures (YTD)	Lapse/Overspent
4000	Grants - Prevention (A.1.2)	$ 28,037,956	$ 28,037,956		$ -	$ 28,037,956	0%	$ -	$ 28,037,956
4000	Grants - Research (A.1.1.)	252,327,738	$ 251,780,707		-	$ 251,780,707	0%	-	251,780,707
	Subtotal - Grants	**$ 280,365,694**	**$ 279,818,663**	**94.16%**	**$ -**	**$ 279,818,663**	**0%**	**$ -**	**$ 279,818,663**
	Grand Totals	**$ 297,085,446**	**$ 297,178,561**	**100.00%**	**$ 11,550,709**	**$ 285,627,852**	**4%**	**$ 11,550,709**	**$ 285,627,852**

Cancer Prevention and Research Institute of Texas

Cancer Prevention and Research Institute Fund Account - 5136

As of November 30, 2018

	11/01/2018-11/30/2018	AY 19 Year to Date as of 11/30/2018
Beginning Balance : 11/01/2018		**$ 600,506**
Increases:		
(1)	$ -	$ -
(2)	-	
Total Increases	**$ -**	**$ 600,506.00**
Reductions:		
Expenditures - Appropriated	$ -	$ -
	$ -	$ -
	$ -	$ -
Total Reductions	**$ -**	**$ -**
Ending Balance, 11/30/2018		**$ 600,506.00**

Note: (1) The Institute received a settlement from the Texas Cancer Coalition (TCC). This amount represents the final distribution and transfer of all funds ($303,877) from the TCC which ceased operations in May 2013. These funds are in the State Treasury but are not appropriated to CPRIT. The beginning balance reflects the transfer of all TCC funds.

Cancer Prevention and Research Institute of Texas

License Plate Trust Fund Account - 0802

As of November 30, 2018

	11/01/2018-11/30/2018	AY 19 Year to Date as of 11/30/2018
Beginning Balance : 11/01/2018		**$ 7,933.16**
Increases:		
(1) License Plate Revenue Received	$ 546.32	$ 1,791.13
Total Increases	**$ 546.32**	**$ 9,724.29**
Reductions:		
Expenditures - Appropriated	$ -	$ -
	-	-
Total Reductions	**$ -**	**$ -**
Ending Balance, 11/30/2018		**$ 9,724.29**

Note:

Cancer Prevention and Research Institute of Texas

Appropriated Receipts - 666

As of November 30, 2018

		11/01/2018-11/30/2018	AY 19 Year to Date as of 11/30/2018
Beginning Balance : 11/01/2018			**$ 24,449.98**
Increases:			
(1)	Product Development Application Fees Received	$ 4,500.00	$ 4,500.00
(2)	Appropriated Receipts applied to payments	$ -	$ -
(3)	Conference Registration Fees	$ -	$ -
(4)	Conference Registration Fees-Credit Card	$ -	$ -
Total Increases		**$ 4,500.00**	**$ 4,500.00**
Reductions:			
	Conference Expenditures - Appropriated	$ -	$ -
	Credit Card Fees Expended	$ -	$ -
	Legal Services Expenses (Application Fees)	$ -	$ -
Total Reductions		**$ -**	**$ -**
Ending Balance, 11/30/2018			**$ 28,949.98**

Begin balance is $24,449.98
Application Fees

Cancer Prevention and Research Institute of Texas

Interest & Sinking Fund Account - 5168

As of November 30, 2018

		11/01/2018-11/30/2018	AY 19 Year to Date as of 11/30/2018
Beginning Balance : 11/01/2018			**$ 226,766.25**
Increases:			
(1)	Revenue Sharing / Royalties	$ 158,886.78	$ 159,264.28
Total Increases		**$ 158,886.78**	**$ 386,030.53**
Reductions:			
	Expenditures - Appropriated	$ -	$ -
		$ -	
		$ -	$ -
Total Reductions		**$ -**	**$ -**
Ending Balance, 11/30/2018			**$ 386,030.53**

Cancer Prevention and Research Institute of Texas
FY 2019, Quarter 1 Performance Measure Report

Measure	Targeted Performance	QTR 1	QTR 2	QTR 3	QTR 4	Sum of QTRs	% of Mandate Attained
Number of Cancer Prevention and Control Services Provided	500,000	197,274				197,274	39.45%
Number of Entities Relocating to TX for Cancer Research Related Projects	2	0				0	0.00%
Annual Age-adjusted Cancer Mortality Rate	156.8	N/A	N/A	N/A	N/A		0.00%
Number of Published Articles on CPRIT-Funded Research Projects	900	N/A	N/A	N/A	N/A		0.00%
Number of New Jobs Created and Maintained	1,335	N/A	N/A	N/A	N/A		0.00%

Variance Explanations

Number of People Served by Institute Funded Prevention and Control Activities
CPRIT grantees deliver education and clinical services throughout the year, so the reported number of people served is not allocated evenly for each fiscal quarter.
Number of Entities Relocating to TX for Cancer Research Related Projects
This output is dependent on the number of companies applying for CPRIT Company Awards that can successfully advance through CPRIT's rigorous review and evaluation process, receive an award and actually relocate operations to Texas.

CPRIT Commercial Paper and G.O. Bond Issuance

Fiscal Year	Amount Appropriated	Dated Issued	Amount Issued	Amount Issued for Fiscal Year	Commercial Paper or GO Bond Issuance	Series	Comments	Interest Rate
2010	$ 225,000,000	September 9, 2009	$ 9,100,000		Commercial Paper Notes	Series A, Taxable		
2010		September 9, 2009	$ 3,600,000		Commercial Paper Notes	Series B, Tax-Exempt	Defeased with cash July 2011	
2010		March 12, 2010	$ 63,800,000		Commercial Paper Notes	Series A, Taxable		
2010		August 26, 2010	$ 148,500,000		Commercial Paper Notes	Series A, Taxable		
				$ 225,000,000				
2011	$ 225,000,000	September 7, 2010	$ 11,800,000		Commercial Paper Notes	Series A, Taxable		
2011		August 10, 2011	$ 51,000,000		G.O. Bonds	Taxable Series 2011	Par amount of new money	Fixed Rate Bonds All-In-True Interest Cost 4.0144%
2011		August 10, 2011	$ 232,045,000		G.O. Bonds (Refunding Bonds)	Taxable Series 2011	Par amount of refunding; Refunded $233.2M of GOCP CPRIT Series A (9/9/09, 3/12/09, 8/26/09, 9/7/10)	Fixed Rate Bonds All-In-True Interest Cost 4.0144%
				$ 62,800,000				
2012	$ 300,000,000	September 7, 2011	$ 3,200,000		Commercial Paper Notes	Series A, Taxable		
2012		December 8, 2011	$ 3,200,000		Commercial Paper Notes	Series A, Taxable		
2012		March 2, 2012	$ 12,300,000		Commercial Paper Notes	Series A, Taxable		
2012		June 21, 2012	$ 15,000,000		Commercial Paper Notes	Series A, Taxable		
2012		August 16, 2012	$ 42,000,000		Commercial Paper Notes	Series A, Taxable		
				$ 75,700,000				
2013	$ 300,000,000	September 6, 2012	$ 9,600,000		Commercial Paper Notes	Series A, Taxable		
2013		May 16,2013	$ 13,400,000		Commercial Paper Notes	Series A, Taxable		
				$ 23,000,000				
2014	$ 300,000,000	November 25, 2013	$ 55,200,000		Commercial Paper Notes	Series A, Taxable		
2014		March 13, 2014	$ 47,000,000		Commercial Paper Notes	Series A, Taxable		
2014		June 17, 2014	$ 60,300,000		Commercial Paper Notes	Series A, Taxable		
2014		July 8, 2014	$ 233,280,000		G.O. Bonds (Refunding Bonds)	Taxable Series 2014	Par amount of refunding; Refunded $237.88M of GOCP CPRIT Series A	Fixed Rate Bonds All-In-True Interest Cost 3.327184%
				$ 162,500,000				
2015	$ 300,000,000	November 5, 2014	$ 57,600,000		Commercial Paper Notes	Series A, Taxable		
2015		April 29, 2014	$ 112,000,000		Commercial Paper Notes	Series A, Taxable		
2015		June 26, 2015	$ 75,000,000		Commercial Paper Notes	Series A, Taxable		
				$ 244,600,000				

CPRIT Commercial Paper and G.O. Bond Issuance

Fiscal Year	Amount Appropriated	Dated Issued	Amount Issued	Amount Issued for Fiscal Year	Commercial Paper or GO Bond Issuance	Series	Comments	Interest Rate
2016	$ 300,000,000	September 22, 2015	$ 55,400,000		Commercial Paper Notes	Series A, Taxable		
2016		October 29, 2015	$ 300,000,000		G.O. Bonds (Refunding Bonds)	Taxable Series 2015C	Par amount of refunding; Refunded $300M of GOCP CPRIT Series A	Fixed Rate Bonds All-In-True Interest Cost 3.299867%
2016		October 29, 2015	$ 69,800,000		G.O. Bonds	Taxable Series 2015C	Par amount of new money: Disbursed to CPRIT January 2016	Fixed Rate Bonds All-In-True Interest Cost 3.299867%
2016		May 16, 2016	$ 92,100,000		Commercial Paper Notes	Series A, Taxable		
2016		August 29, 2016	$ 60,000,000		Commercial Paper Notes	Series A, Taxable		
				$ 277,300,000				
2017	$300,000,000	October 19, 2016	$ 58,000,000		Commercial Paper Notes	Series A, Taxable		
2017		January 5, 2017	$ 58,900,000		Commercial Paper Notes	Series A, Taxable		
2017		February 8, 2017	$ 269,000,000		G.O. Bonds (Refunding Bonds)	Taxable Series 2017	Par amount of refunding: Refunded $269M of GOCP CPRIT Series A	Fixed Rate Bonds All-In-True Interest Cost 3.4622%
2017		February 8, 2017	$ 106,000,000		G.O. Bonds	Taxable Series 2017	Par amount of new money	Fixed Rate Bonds All-In-True Interest Cost 3.4622 %
				$ 222,900,000				
2018	$300,000,000	September 29, 2017	$ 68,200,000		Commercial Paper Notes	Series A, Taxable		
2018		March 8, 2018	$ 99,000,000		Commercial Paper Notes	Series A, Taxable		
2018		July 11, 2018	$ 55,000,000		Commercial Paper Notes	Series A, Taxable		
2019		September 11, 2018	$ 222,200,000		G.O. Bonds (Refunding Bonds)	Taxable Series 2018	Par amount of refunding	Fixed Rate Bonds All-in-True Interest Cost 3.720609%
				$ 222,200,000				
2019	$300,000,000	September 11, 2018	$ 75,975,000		G.O. Bonds	Taxable Series 2018	Par amount of new money	Fixed Rate Bonds All-in-True Interest Cost 3.720609%
				$ 75,975,000				
TOTAL ISSUED TO DATE				**$ 1,591,975,000**				